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42 CFR Parts 403, 405, 410, et al.
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; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 414, 425, and 498

[CMS–1612–P]

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: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. See the Table of Contents for a listing of the specific issues addressed in this proposed rule.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 2, 2014.

ADDRESSES: In commenting, please refer to file code CMS–1612–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1612–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1612–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Gail Addis, (410) 786–4552, for issues related to the refinement panel or for any physician payment issues not identified below.

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.

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, for issues related to local 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.

Rashaan Byers, (410) 786–2305, 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.

SUPPLEMENTARY INFORMATION:

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,

Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

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

AAA Abdominal aortic aneurysms
ACO Accountable care organization
AMA American Medical Association
ASC Ambulatory surgical center
ATA American Telehealth Association
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CAD Coronary artery disease
CAH Critical access hospital
CBSA Core-Based Statistical Area
CCM Chronic care management
CEHRT Certified EHR technology
CF Conversion factor
CG–CAHPS Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS Clinical Laboratory Fee Schedule
CNM Certified nurse-midwife
CP Clinical psychologist
CPC Comprehensive Primary Care
CPEP Clinical Practice Expert Panel
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2013 American Medical Association. All rights reserved.*)
CQM Clinical quality measure
CSW Clinical social worker
CT Computed tomography
CY Calendar year
DFAR Defense Federal Acquisition Regulations
DHS Designated health services
DM Diabetes mellitus
DSMT Diabetes self-management training
eCQM Electronic clinical quality measures
EHR Electronic health record
E/M Evaluation and management
EP Eligible professional
eRx Electronic prescribing
ESRD End-stage renal disease
FAR Federal Acquisition Regulations
FFS Fee-for-service
FQHC Federally qualified health center
FR **Federal Register**
GAF Geographic adjustment factor
GAO Government Accountability Office
GPCI Geographic practice cost index
GPO Group purchasing organization
GPRO Group practice reporting option
GTR Genetic Testing Registry
HCPCS Healthcare Common Procedure Coding System
HHS [Department of] Health and Human Services
HOPD Hospital outpatient department
HPSA Health professional shortage area
IDTF Independent diagnostic testing facility
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IWPUT Intensity of work per unit of time
LCD Local coverage determination
MA Medicare Advantage
MAC Medicare Administrative Contractor
MAP Measure Applications Partnership
MAPCP Multi-payer Advanced Primary Care Practice
MAV Measure application validity [process]
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
MP Malpractice
MPPR Multiple procedure payment reduction
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Areas
MSPB Medicare Spending per Beneficiary
MSSP Medicare Shared Savings Program
MU Meaningful use
NCD National coverage determination
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NP Nurse practitioner
NPI National Provider Identifier
NPP Nonphysician practitioner
NQS National Quality Strategy
OACT CMS's Office of the Actuary
OBRA '89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239)
OBRA '90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101- 508)
OES Occupational Employment Statistics
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
PA Physician assistant
PAMA Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)
PC Professional component
PCIP Primary Care Incentive Payment
PE Practice expense
PE/HR Practice expense per hour
PEAC Practice Expense Advisory Committee
PECOS Provider Enrollment, Chain, and Ownership System
PFS Physician Fee Schedule
PLI Professional Liability Insurance
PMA Premarket approval
PQRS Physician Quality Reporting System
PPIS Physician Practice Expense Information Survey
PT Physical therapy
PY Performance year
QCDR Qualified clinical data registry
QRUR Quality and Resources Use Report
RBRVS Resource-based relative value scale
RFA Regulatory Flexibility Act
RHC Rural health clinic
RIA Regulatory impact analysis
RUC American Medical Association/ Specialty Society Relative (Value) Update Committee
RUCA Rural Urban Commuting Area
RVU Relative value unit
SBA Small Business Administration
SGR Sustainable growth rate
SIM State Innovation Model
SLP Speech-language pathology
SMS Socioeconomic Monitoring System
SNF Skilled nursing facility
TAP Technical Advisory Panel
TC Technical component
TIN Tax identification number
UAF Update adjustment factor

UPIN Unique Physician Identification Number
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2015 PFS proposed rule, refer to item CMS–1612–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this proposed rule and posted on the CMS Web site identified above should contact *Larry.Chan@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 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 proposed rule would revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These changes would be applicable to services furnished in CY 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 proposed rule, we propose 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 proposed rule 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 to Core-Based Statistical Areas for Ambulance Payment.
- Updating the—
  - ++ Physician Compare Web site.
  - ++ Physician Quality Reporting System.
  - ++ Medicare Shared Savings Program.
  - ++ Electronic Health Record (EHR) Incentive Program.
- Value-Based Payment Modifier and the Physician Feedback Program.

3. Summary of Costs and Benefits

The Act requires that annual adjustments to PFS RVUs 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. The most significant impacts are for radiation therapy centers and radiation oncology for which there would be decreases of 8 and 4 percent, respectively. These reductions primarily stem from a proposal discussed in section II.A. to consider an equipment item as indirect rather than direct practice expense. Payment for chronic care management (CCM) services is projected to have a positive effect on family practice, internal medicine, and geriatrics. This proposed rule includes new proposed MP RVUs based upon CY 2015 five-year review of MP RVUs. For most specialties, the proposed revisions for the five-year review of MP RVUs would result in minor overall changes in RVUs, with only ophthalmology (-2 percent) having a projected change of at least 2 percent.

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

1. Development of the Relative Values

a. Work RVUs

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

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations

received from the American Medical Association/Specialty Society Relative Value Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

b. Practice Expense RVUs

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

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

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

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

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

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

c. Malpractice RVUs

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

d. Refinements to the RVUs

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

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

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

With regard to MP RVUs, we completed five-year reviews of MP that were effective in CY 2005 and CY 2010. This proposed rule includes a proposal for 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.1. of this proposed rule, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs would cause expenditures for the year to change by more than $20 million, we make

adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each 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 proposed rule for more information about GPCIs.)

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The 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:

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

3. Separate Fee Schedule Methodology for Anesthesia Services

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

4. Most Recent Changes to the Fee Schedule

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.2 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 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 their 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 electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT 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 networks. 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 ONC's HIT Certification Program and expand HIT certification, ONC has issued a proposed rule concerning a voluntary 2015 Edition of EHR certification criteria, which would more easily accommodate the certification of HIT used in all health care settings where health care providers are not typically eligible for incentive payments under the EHR Incentive Programs, to facilitate greater HIE across the entire care continuum. We believe that HIE and the use of certified EHRs can effectively and efficiently help 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). More information on the Voluntary 2015 Edition EHR Certification Criteria proposed rule is available at *http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations.*

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 MP 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 with respect to 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, equipment, and supplies) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this proposed rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the 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 under the bottom-up methodology.)

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 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 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 NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

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

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

Modifier	Description	Volume adjustment	Time adjustment
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

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

For anesthesia services, we do not apply adjustments to volume since 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 proposed 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 solicit comment regarding reliable data on maintenance costs that vary for particular equipment items.

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 solicit comment on adjusting our cost formula to include equipment costs that do not vary based on the equipment time.

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 (percent)
<$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
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	5.10	5.10	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	.53	.53	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	6.92	6.92	0.00	0.09	0.09	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	85.45	13.19	13.19	0.00	6.38	6.38	0.00
(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	=Lab * Dir Adj	=(1)*(5)	7.86	45.72	3.39	3.39	0.00	3.01	3.01	0.00
(7) Adjusted Supplies	Steps 2–4	=Eqp * Dir Adj	=(2)*(5)	1.76	4.33	.31	.31	0.00	.70	.70	0.00
(8) Adjusted Equipment	Steps 2–4	=Sup * Dir Adj	=(3)*(5)	.10	0.34	4.08	4.08	0.00	0.05	0.05	0.00
(9) Adjusted Direct	Steps 2–4		=(6)+(7)+(8)	9.72	50.40	7.78	7.78	0.00	3.77	3.77	0.00
(10) Conversion Factor (CF)	Step 5	PFS		35.8228	35.8228	35.8228	35.8228	35.8228	35.8228	35.8228	35.8228
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.22	1.28	0.09	0.09	0.00	0.08	0.08	0.00
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.01	0.01	0.00	0.02	0.02	0.00
(13) Adj. equipment cost converted.	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.11	0.11	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.27	1.41	0.22	0.22	0.00	0.11	0.11	0.00
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.25	0.17	0.29	0.29	.29	.29	.29	.29
(17) Ind_pct	Steps 6,7	Surveys		0.75	.83	.71	.71	.71	.71	.71	.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	.53	.53	0	0.26	0.26	0
(20) Ind. Alloc. Formula (2nd part)	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.31	0.09	0.22	0.25	0.08	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+(21)	1.79	40.42	.84	.62	0.22	0.51	0.34	0.17

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

		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
(23) Indirect Adjustment (Ind. Adj.)	Steps 9–11.	See Footnote**	.....	.3813	.3813	.3813	.3813	.3813	.3813	.3813	.3813
(24) Adjusted Indirect Allocator	Steps 9–11.	=Ind Alloc * Ind Adj	.....	0.68	15.41	.32	.24	0.08	0.20	0.13	.06
(25) Ind. Practice Cost Index (IPCI).	Steps 12–16.	.....	.....	1.07	0.75	.99	.99	.99	0.91	0.91	0.91
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24)*(25)	0.73	11.59	.32	.24	0.08	0.18	0.12	0.06
(27) PE RVU	Step 18	=(Adj Dir + Adj Ind) * Other Adj.	=((14)+(26)) * Other Adj).	1.01	13.05	.53	.45	.08	.29	.23	0.06

* The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [step2]/[step3].
** The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [step9]/[step10].
Note: The use of any particular conversion factor (CF) in this table to illustrate the PE calculation has no effect on the resulting RVUs.

3. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2015 proposals and revisions related to direct PE inputs for specific services. The proposed direct PE inputs are included in the proposed rule CY 2015 direct PE input database, which is available on the CMS Web site under downloads for the CY 2015 PFS proposed rule 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 propose to accept, without refinement, the RUC recommendation to adjust these clinical labor minutes as indicated in Table 5 as ''Change to Clinical Labor Time.'' The CY 2015 direct PE database reflects these proposed changes and is available on the CMS Web site under the supporting data files for the CY 2015 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

TABLE 5—CODES WITH PROPOSED 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

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 future recommendations would use 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 these services. Therefore, we propose 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 proposed revised moderate sedation input package would be applied to relevant codes as we review them through future notice and comment rulemaking. 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.

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

The RUC has 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 that 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, we are unable to determine the appropriate pricing to use for the inputs. We propose 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, we propose 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 propose to allocate the full clinical labor intraservice time to ED021, except when there is no clinical labor, in which case we propose to allocate the intraservice work time to ED021. For services valued only in the facility setting, we propose 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 PROPOSED TO BE 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 proposed 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 proposed change to digital inputs would take effect beginning January 1, 2015. We also believe 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 seek comment on whether the computer workstation, which we propose 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.

TABLE 7—CODES CONTAINING FILM INPUTS BUT EXCLUDED FROM THE RUC RECOMMENDATION—Continued

HCPCS	Short descriptor
91120	Rectal sensation test.
91122	Anal pressure record.
91132	Electrogastrography.
91133	Electrogastrography w/test.
92521	Evaluation of speech fluency.
92523	Speech sound lang comprehend.
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 note 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 agree 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 recognize 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 are 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 refer 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 are displaying this information as we attempt to increase the transparency of the direct PE database. We hope that this modification could 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 are seeking comments on the feasibility of this approach. We note that we are not proposing to make any changes to PE inputs for CY 2015 based on this proposed modification to the design of the direct PE input database.

The CY 2015 direct PE database reflects these proposed changes and is available on the CMS Web site under the supporting data files for the CY 2015 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

d. Inputs for Digital Mammography Services

Mammography services are currently reported by and paid for 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 the G-codes for 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 pay for mammography billed using the CPT codes when the services were furnished with film technology (77055 mammogram one breast; 77056 mammogram both breasts; 77057 mammogram screening). 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 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 what the RUC has indicated regarding the use of digital technology. It appears that the typical mammography service is furnished using digital technology. As such, we do not believe there is a reason to continue the separate use of the CPT codes and the 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 are proposing to delete the mammography G-codes beginning for CY 2015 and to pay all mammography using the CPT codes.

Although we believe that the CPT codes should now be used to report all mammography services, we have 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 during this time, we do not believe it would be appropriate to retain the current values for the CPT codes. Therefore, we are proposing to value the CPT codes using the RVUs previously established for the G-codes. We believe 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.3.b.(4) of this proposed rule, we are proposing these CPT codes as potentially misvalued and requesting that the RUC and other interested stakeholders review these services in terms of appropriate work RVUs, work time assumptions and direct PE inputs.

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. Moreover, it is difficult to distinguish the cost of the vault from the cost of the building. In response to this action, 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 believe 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 do not represent direct medical equipment costs in our established PE methodology. Therefore we believe 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 infrastructure costs based on equipment needs Therefore, we propose to remove the radiation treatment vault as a direct PE input from the radiation treatment procedures listed in Table 8, because we believe that the vault is not, itself, medical equipment, and therefore, is accounted for in the indirect PE methodology.

TABLE 8—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.

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 are proposing a correction to the clinical labor type for this service.

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 are proposing to move the RN time allocated to these procedures to the facility setting. The PE RVUs listed in Addendum B reflect these technical corrections.

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 proposed 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 Web site under the supporting data files for the CY 2015 PFS proposed rule 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*.

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 propose 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 previously stated our difficulty in obtaining accurate pricing information. We have also made clear that 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 note that we continue to have difficulty determining the best way to use the invoices that we receive. In all cases, we attempt to use the price that appears most representative, but it can be difficult to ascertain whether the prices on particular invoices are typical. For example, in some cases, we receive multiple invoices, but are only able to use one of them because the other invoices include additional items and do not separately identify the price of the item in question. In other cases, we receive multiple invoices at one price, which suggests that this price is likely a typical one. In other cases, we receive invoices for items already in the direct PE database that are based on a recent invoice. In these cases, it is not clear whether the new, usually higher priced, invoice reflects a more accurate price than the current price, but we need to determine whether to substitute the new price for the existing price, maintain the existing price, or average the two prices. We continue to seek stakeholder input on the best approach to using the small sample of invoices that are provided to us through this process.

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 are proposing to update the prices for both of these items based on these recommendations. The CY 2015 direct PE database reflects these proposed changes and is available on the CMS Web site under the supporting data files for the CY 2015 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

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 9. We propose to accept this recommendation, but seek 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 proposed change and is available on the CMS Web site under the supporting data files for the CY 2015 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*.

TABLE 9—STANDARD CONTRAST IMAGING SUPPLY PACKAGE

Medical supply description	CMS supply code	Unit	Quantity	Price
Imaging w/Contrast—Standard Package				
Kit, IV starter	SA019	Kit	1	$1.368
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				6.824

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

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 these codes in future rulemaking.

Most commenters suggested 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 have no indication that the direct PE inputs included in the CPT codes do not reflect the typical resource inputs involved in furnishing an SRS service. Therefore, we propose to recognize only the CPT codes for payment of SRS services, and to delete the G-codes used to report robotic delivery of SRS.

k. Inclusion of Capnograph for Pediatric Polysomnography Services

We are proposing 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). We understand that capnography is a required element of sleep studies for patients younger than 6 years, and propose 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 propose to price EQ358 at $4,534.23.

l. Nonfacility Direct PE Inputs for Intravascular Ultrasound

A stakeholder requested that we establish nonfacility PE RVUs for CPT code 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure)) and 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure)). We seek comment regarding whether it is appropriate to have nonfacility PE RVUs for this code and if so what inputs should assigned to this code.

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, 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 note 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 CY 2014 rulemaking 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 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 are not proposing 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 a 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) 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 proposed rule, 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 experience has also 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 also 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.

Section 220 of the PAMA also provides authority to use alternative approaches to establish practice expense 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 PFS PE RVUs, and we want to be sure we are aware of these prior to considering or developing any future proposal relying on those data. Therefore, we are seeking 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 note 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 are particularly interested 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 urge 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.

In addition to soliciting comments as noted above, we continue to seek a better understanding regarding the growing trend toward hospital acquisition of physician offices and

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 physician 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 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 does 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 addressed this issue as it relates to accurate valuation of visits within the post-operative period of 10- and 90-day global codes in section II.B.4 of this proposed rule.

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 (73 FR 43302). 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 believe 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 physician and hospital services furnished in an off-campus provider-based department of a hospital. 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 are proposing 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 1834(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 are seeking additional comment on whether a code modifier is the best mechanism for collecting this service-level information.

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 MP. Section 1848(c)(1)(A) of the Act defines the work component to include ''the portion of the resources used in furnishing the service that reflects work 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 proposed rule 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 proposed rule 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) to the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.B. of this proposed rule, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), 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 PFS, 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 the initial recommendations, ''CMS and the RUC have taken several steps to improve the review process.'' Also, since that time 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 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 also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

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

Since CY 2009, as a part of the annual potentially misvalued code review and the 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 and have listed work time).

In the CY 2014 final rule with comment period, we finalized for review a list of potentially misvalued services that included 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 evaluation and management (E/M) visit information and work time for approximately 100 global surgery codes. In CY 2014, we also considered a proposal to limit Medicare PFS payments for services furnished in a nonfacility setting when the PFS payment would exceed the combined Medicare payment under the PFS to the practitioner and facility payment made to either the ASC or hospital outpatient. 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 in section II.A. of this proposed rule.

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 to be appropriate to facilitate the validation of RVUs of services.

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

Since that time, we have 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 for PFS services. 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. In its efforts to collect primary data on the time involved in PFS services, the Urban Institute has encountered numerous challenges. An interim report, Development of a Model for the Valuation of Work Relative Value Units, discusses the challenges encountered in collecting objective time data and offers some thoughts on how these can be overcome. This interim report is on the CMS Web site 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 Web site.

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

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.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous

valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.

• Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.

• Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting System (PQRS) databases).

• National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

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

During the comment period on the CY 2014 final rule with comment period, we received nominations and supporting documentation for two codes to be considered as potentially misvalued codes. We evaluated the supporting documentation for each nominated code to ascertain whether the submitted information demonstrated that the code should be proposed as potentially misvalued.

CPT code 41530 (submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session) was nominated for review as a potentially misvalued code. The nominator stated that CPT code 41530 is misvalued because there have been changes in the PE items used in furnishing the service. The nominator specifically requested that the SD109 probe (probe, radiofrequency, 3 array (StarBurstSDE)) be replaced with a more typically used probe, which costs less, and that a replacement be used for equipment code EQ214 (radiofrequency generator) to reflect a more appropriate input based on current invoices. We are proposing this code as a potentially misvalued code.

CPT code 99174 (instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral) was also nominated for review as a potentially misvalued code. The nominator asserted that CPT code 99174 is misvalued because of outdated capital equipment inputs and the removal of supply code SK110 (fee, image analysis) from the code's direct PE inputs. (The latter change was proposed and finalized during CY 2014 notice and comment rulemaking). In establishing our public nomination process, we specified that the we would only consider nominations of active codes that are covered by Medicare at the time of the nomination stating, ''We also are limiting the review of RVUs to codes that are active, covered by Medicare, and for which the RVUs are used for payment purposes under the PFS so that resources are not expended on the review of codes with RVUs that have no financial impact on the PFS.'' (76 FR 73059). CPT code 99174 is non-covered on the PFS and therefore does not meet the criteria for review as a potentially misvalued code. Accordingly, we are not proposing CPT code 99174 as a potentially misvalued code.

b. Potentially Misvalued Codes

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

We are proposing the approximately 65 codes listed in Table 10 as potentially misvalued codes as a prioritized subset of codes of the newly established statutory category, ''codes that account for the majority of spending under the physician fee schedule.'' As we identify potentially misvalued codes, we prioritize codes that are important to the Medicare program and its beneficiaries, and codes that account for a high level of Medicare expenditures meet this criterion. However, through our usual identification potentially misvalued codes it is possible to miss certain services that are important to a segment of Medicare practitioners and beneficiaries because the specialty that typically furnishes the service does not have high volume relative to the overall PFS utilization. To capture such services in developing this list, we looked at high expenditure services by specialty using a similar approach to the one we used in CY 2012. We believe it is appropriate to repeat this type of analysis periodically.

To develop the CY 2015 proposed list in this category, we began by identifying the top 20 codes by specialty in terms of allowed charges. For this analysis, we used the same specialties as used for the impact analysis in section VI. of this proposed rule. We excluded codes from our proposed potentially misvalued list that we have reviewed since CY 2009, with fewer than $10 million in allowed charges, and that describe anesthesia or E/M services. We excluded E/M services from the list of proposed potentially misvalued codes for the same reasons that we excluded them in the CY 2012 analysis, which we explained in the CY 2012 final rule with comment period (76 FR 73062 through 73065).

We believe that a review of the codes in Table 10 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 are proposing the codes listed in Table 10 as potentially misvalued.

TABLE 10—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE 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.
77263	Radiation therapy planning.
77334	Radiation treatment aid(s).
78452	Ht muscle image spect mult.

TABLE 10—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE SPECIALTY SCREEN—Continued

HCPCS	Short descriptor
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.

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

For CY 2014, we established interim final values 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 below 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 since the last time they were valued 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 believed that 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 62310, 62311, and 62318 and a portable C-arm for 62319.

We received thousands of comments objecting to the CY 2014 interim final values for these codes, many citing concerns with patient access and with the potential for the payment reductions under the PFS to inappropriately incentivize the use of the hospital setting or to encourage the use of other injections. Some suggested these payment rates might affect the rate of opioid use. Although most comments did not address the accuracy of the relative value inputs used in determining PFS payment rates, those that did most often objected to our valuations of the work RVUs and recommended that we instead accept the RUC recommendations. Several commenters objected to our rationale for setting the interim final work RVUs lower than the RUC-recommended values primarily based upon the reduction in time. Commenters gave two primary reasons why this reduction was inappropriate. Some pointed out that a reduction in work based upon a reduction in time presumes that the existing time is correct. These commenters asserted that the existing times were not correct for these codes. For example, the RUC noted that the CY 2013 survey times were from the original 1999 survey and were an outlier when compared to the previously reported code's original Harvard-valued total time of 42 minutes. One commenter noted that CMS indicates that in setting work values, the agency considers time, mental effort, professional judgment, technical skill, physical effort and stress due to risk; but in this case, rather than following our process, we only considered time. Others also said that we did not take into account the intensity, complexity, or risk of performing epidural injections. Commenters disagreed with the use of the lowest RUC survey value as the basis for the work valuation. One commenter said that we failed to explain adequately why our work RVUs were below those recommended by the RUC. One recommended that we assign values more similar to those used for paravertebral injections.

Two commenters stated that critical PE inputs, including an epidural needle, loss or resistance syringe and spinal needle, were missing from the valuation. One commenter indicated that a radiographic-fluoroscopic room should be included for CPT codes 62310, 62311 and 62318; and a mobile C-Arm should be included for CPT code 62319. Another commenter requested the decreases in the PE RVUs be phased in over a period of years.

Several commenters objected to the use of the interim final process for valuing these codes, citing the lack of opportunity for public comment and the lack of time to adequately prepare before the cuts to reimbursement took effect. Some suggested a delay in implementation.

Lastly, several commenters requested refinement panel review of these codes.

After analyzing the comments and considering valuation of these codes, we believe that we need to reassess our valuation of these codes and require additional information in order to do so. Our data show that these epidural codes are frequently billed with imaging guidance. For example, CPT code 62310 was billed with CPT code 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)) 79 percent of the time in the nonfacility setting in CY 2013. CPT code 62319, which is the epidural injection code that is least frequently billed with CPT code 77003 in the nonfacility setting, was still billed with this guidance code 40 percent of the time. These codes were also frequently billed with image guidance in the facility setting. CPT codes 62310 and 62311 were billed with CPT code 77003, 79 percent and 74 percent of the time,

respectively in CY 2013. However, in the facility setting CPT codes 62318 and 62319 were much less frequently billed with CPT code 77003, only 3 percent and 11 percent, respectively. In addition, these four epidural injection codes are sometimes billed with other fluoroscopic or imaging guidance codes. Based on the frequency with which these codes are reported with fluoroscopic guidance codes, it appears that fluoroscopic guidance is both typically used and typically reported separately in conjunction with the epidural injection services.

As we considered the concerns raised regarding the CY 2014 payment changes for the epidural injection procedures, we looked at the values for other injection procedures. Other injection procedures, including some recommended by commenters for use as a reference in valuing these epidural injection codes, include the work and PEs of image guidance in the injection code. For example, transforaminal injections, CPT codes 64479 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level), 64480 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (List separately in addition to code for primary procedure)), 64483 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level) and 64484 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)) include the image guidance in the injection code. Similarly, the paravertebral injections, CPT code 64490 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level), 64491 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)), 64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)), 64493 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level), 64494 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for the primary procedure)) and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)(List separately in addition to code for primary procedure)) each include the image guidance bundled in the injection CPT code.

Based upon our analysis of the Medicare claims data and comments received on the CY 2014 final rule with comment period, it appears that these codes are typically furnished with imaging guidance. Thus, we believe it would be appropriate for the injection and imaging guidance 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 do not believe the epidural injection codes can be appropriately valued without considering the typical use of image guidance. We also believe this 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 believe more information is needed. Accordingly, we propose to include CPT codes 62310, 62311, 62318 and 62319 on the potentially misvalued code list so that we can obtain information to support their valuation with the image guidance included. In the meantime, we are proposing to revert to the CY 2013 input values for CPT codes 62310, 62311, 62318 and 62319 for CY 2015. Specifically, we will use the CY 2013 work RVUs, work times, and direct PE inputs to establish payment rates for CY 2015. The work, PE, and MP RVUs for these codes are listed in Addendum B and the time values for all CY 2015 codes are listed in the file ''CY 2015 PFS Work Time,'' available on the CMS Web site under downloads 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 direct PE inputs are displayed the file ''CY 2015 PFS Direct PE Inputs,'' available on the CMS Web site under downloads for the CY 2015 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Because it is clear that the proposed PE inputs for the epidural injection codes include items that are specifically related to image guidance, such as the radiographic fluoroscopic room, we believe separate reporting of the image guidance codes would overestimate the resources used in furnishing the two services together. To avoid this situation, we are also proposing to prohibit the billing of image guidance codes in conjunction with these four epidural injection codes. We believe our two-tiered proposal to utilize CY 2013 input values for this code family, while prohibiting the separate billing of imaging guidance codes in conjunction with epidural injection, would best ensure that appropriate reimbursement continues to be made while we gather additional information and consider the best way to value these services.

With regard to comments about the time for responding to the interim values, we would refer to section II.F of this proposed rule, which discusses a proposal to make changes in the process used for establishing revised values for codes such as these.

With regard to the request for refinement, we are denying this request as the comments do not demonstrate that the requirements for refinement were met. Moreover, since we are proposing different values for these codes for CY 2015 (using CY 2013 inputs) there would be no purpose for refinement as the public comment period for this proposed rule will provide the opportunity for the public to share any relevant information on our proposed values.

(3) Neurostimulator Implantation—CPT Codes 64553 and 64555

A stakeholder raised questions regarding whether CPT codes 64553 (Percutaneous implantation of neurostimulator electrode array; cranial nerve) and 64555 (Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)) included the appropriate direct PE inputs when furnished in the nonfacility setting. It appears that these inputs have not been evaluated recently and, therefore, we are nominating these codes as potentially misvalued for the purpose of

ascertaining whether or not there are nonfacility direct PE inputs that are not included in the direct PE inputs that are typical supply costs for these services.

(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 be used for digital technology in response to special payment rules for digital mammography included in the Medicare Benefit Improvements and Protection Act of 2000.

As discussed in section II.A., 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 the typically used in imaging.

Our data confirms that the overwhelming majority of all mammography is digital. As a result, we are proposing that the CPT codes 77055, 77056 and 77057 be used for reporting mammography to Medicare regardless of whether film or digital technology is used, and to delete the HCPCS G-codes G0202, G0204, and G0206. We are proposing, for CY 2015, to value the CPT codes using the values established for the digital mammography G-codes since digital technology is now the typical service. (See section II.A. of this proposed rule for more discussion of this proposal.) In addition, since the G-codes values that we propose to use for the CPT codes for CY 2015 have not been reviewed since they were created in CY 2002, we are proposing to include CPT codes 77055, 77056, and 77057 on the list of potentially misvalued codes.

(5) Abdominal Aortic Aneurysm Ultrasound Screening—G0389

When Medicare began paying for abdominal aortic aneurysm (AAA) ultrasound screening in CY 2007, we created HCPCS code G0389 (Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening), and 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, based on a RUC recommendation, we proposed to replace the ultrasound room included as a direct PE input for CPT code 76775 with a portable ultrasound unit. Since all the RVUs (including the PE RVUs) for G0389 were crosswalked from CPT code 76775, the proposed PE RVUs for G0389 in the CY 2014 proposed rule were reduced significantly as a result of this change to the direct PE inputs for 76775. However, we did not discuss the applicability of this change to G0389 in the proposed rule's preamble 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 the corresponding PE RVUs for G0389 were also reduced.

Subsequent to the publication of the CY 2014 final rule, a stakeholder suggested that the reduction in the RVUs for G0389 did not accurately reflect the resources involved in furnishing the service and asked that CMS consider using an alternative crosswalk. Specifically, the stakeholder stated that the type of equipment typically used in furnishing G0389 is different than that used for CPT code 76775, the time involved in furnishing G0389 is greater than that of CPT code 76775, and the specialty that typically furnishes G0389 is different than the one that typically furnishes CPT code 76775. The stakeholder suggested an alternative crosswalk of CPT code 76705 (Ultrasound, abdominal, real time with image documentation; limited (eg, single organ, quadrant, follow-up)).

After considering the issue, we are proposing G0389 as a potentially misvalued code and seeking recommendations regarding the appropriate inputs that should be used to develop RVUs for this code. We have not reviewed the inputs used to develop RVUs for this code since it was established in CY 2007 and the RVUs were directly crosswalked from 76705. Based on the issues raised by stakeholders, we believe that we should value this code through our standard methodologies, including the full PE RVU methodology. In order to do so, we are proposing to include this code on our list of proposed potentially misvalued codes and seek input from the public and other stakeholders, including the RUC, regarding the appropriate work RVU, time, and direct PE inputs that reflect the typical resources involved in furnishing the service.

Until we receive the information needed to revalue this service, we are proposing to maintain the work RVU for this code and revert to the same PE RVUs we used for CY 2013, adjusted for budget neutrality. We are proposing MP RVUs based on the five-year review update process as described in section II.C of this proposed rule. We believe this valuation will ameliorate the effect of the CY 2014 reduction in G0389 that resulted from reflection of the change in RVUs for the crosswalked code while we assess the valuation of this code through our usual methodologies. The proposed PE RVUs are contained in Addendum B available on the CMS Web site under downloads for the CY 2015 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(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. In considering these discussions and our review, we have become aware that the

current coding structure may be confusing, especially since the number of specimens associated with prostate biopsies is relatively homogenous. For example, G0416 (10–20 specimens) represents the overwhelming majority of all Medicare claims submitted for the four G-codes. Therefore, in the interest of both establishing straightforward coding and maintaining accurate payment, we believe it would be appropriate to use only one code to report prostate biopsy pathology services. Therefore, we propose 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 propose to revise G0416 for use to report all prostate biopsy pathology services, regardless of the number of specimens, because we believe this will eliminate the possible confusion caused by the coding while maintaining payment accuracy.

Based on our review of medical literature and examination of Medicare claims data, we believe that the typical number of specimens evaluated for prostate biopsies is between 10 and 12. Since G0416 is the code that currently is valued and used for between 10 and 12 specimens, we are proposing to use the existing values for G0416 for CY 2015.

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

(7) Obesity Behavioral Group Counseling—GXXX2 and GXXX3

Under 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 has been 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 are creating two new HCPCS codes for the reporting and payment of group behavioral counseling for obesity. Specifically, we are creating 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). The coverage requirements for these services would remain in place, as described in the National Coverage Determination for Intensive Behavioral Therapy for Obesity cited in this section of the proposed rule. The practitioner furnishing these services would report the relevant group code for each beneficiary participating in a group therapy session.

We believe 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, which is a 15-minute code with a work RVU of 0.45. Therefore, to develop proposed work RVUs for HCPCS codes GXXX2 and GXXX3 we scaled the work RVU of HCPCS code G0447 to reflect the differences in the codes in terms of the time period covered by the code and the typical number of beneficiaries per session. Adjusting the work RVU for the longer time of the group codes results in a work RVU of 0.90 for a 30-minute session. Since the services described by GXXX2 and GXXX3 will be billed per beneficiary receiving the service, the work RVUs and work time that we are proposing for these codes are based upon the typical number of beneficiaries per session, 4 and 9, respectively. Accordingly, we are proposing 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.

Using the same logic, we are proposing 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 described by the new codes. The proposed direct PE inputs for these codes are included in the CY 2015 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2015 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/.* We are also proposing 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 request public comment on these proposed values for HCPCS codes GXXX2 and GXXX3.

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 provided 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.

These unique characteristics have contributed to the significant and numerous concerns that have been raised regarding the accuracy of payment for global codes—especially those that include 10- and 90-day post-operative periods. In the following paragraphs, we address a series of concerns regarding these codes, including: the fundamental difficulties in establishing appropriate relative values for these packages, the potential inaccuracies in the current information used to price these services, the limitations on appropriate pricing in the future, the potential for these 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.

Independently, concerns such as these could be seen as issues that arise when developing many different payment mechanisms, for example: making fee-for-service payment rates, making single payments for multiple services, or paying practitioners 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 these multi-layered 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 the 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 other PFS services 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 an annual 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 that ten post-operative visits is typical, but practitioners reporting the code 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. Although such a mechanism is common in other bundled payment systems, there is no such mechanism under the PFS. 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 services 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 provided 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. Although such information would be available for developing payment rates for bundled services through other Medicare payment systems, 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 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 proposed rule, 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 Transition 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 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 are proposing to retain global bundles for surgical services, but to refine bundles by transitioning 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 transitioning 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 seek 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 seek 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 seek 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 seek 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 are also seeking 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 conducting 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 seek 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 essential to ensuring work RVU relativity across these services. We also believe that these data will be necessary 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 are 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.

While we believe these are plausible options for the revaluation of these services, we believe there may be others. Therefore, we seek 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 seek 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 are proposing to transition 10-day global periods in 2017 and 90-day global periods in 2018, we seek comment on whether we should consider implementing the transition more or less quickly and over one or several years. We also seek comment regarding the appropriate valuation of new, revised, or potentially misvalued 10- or 90-day global codes before implementation of this proposal.

5. Improving the Valuation of the Global Package

In the CY 2013 proposed rule, we sought comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package. In addition to receiving the broader comments on measuring post-operative work, we also received a comment from the RUC saying that the hospital inpatient and discharge day management services included in the global period for many surgical procedures were inadvertently removed from the time file in 2007. With its comment letter, the RUC sent us a data file with updated times for these post-operative visits for some services that displayed zero hospital inpatient or discharge day visits in the CMS time file. After extensive review, we concluded that the data were deleted from the time file due to an inadvertent error as noted by the RUC. Therefore, during CY 2014 PFS rulemaking we finalized a proposal to replace the missing postoperative hospital inpatient and discharge day visits for the more than 100 codes that were identified by the RUC.

Since then, the AMA has identified additional codes with data in the work time file that reflects a similar error. Since we believe these global surgery codes are missing postoperative hospital inpatient and discharge day visits due to an inadvertent error, we are proposing to include a corrected number of visits for the codes displayed in Table 11. This proposal would also alter the total time associated with the codes in the work time file.

TABLE 11—PROPOSED WORK TIME CHANGES IN SELECTED GLOBAL SURGICAL PACKAGE VISITS

CPT code	Short descriptor	Visits included in Global Package						CY 2014 time	CY 2015 time
		99231	99232	99233	99238	99291	99292		
19367	Breast reconstruction	3.00			1.00			552.00	590.00
20802	Replantation arm complete	6.00			1.00			1047.00	1041.00
20805	Replant forearm complete	6.00			1.00			1017.00	1012.00
20808	Replantation hand complete	5.00			1.00			1177.00	1112.00
20972	Bone/skin graft metatarsal	5.00			1.00			918.00	898.00
21137	Reduction of forehead				1.00			272.00	310.00
21138	Reduction of forehead				1.00			362.00	400.00
21150	Lefort ii anterior intrusion	1.00			1.00	1.00		542.00	623.00
21159	Lefort iii w/fhdw/o lefort i	3.00			1.00	2.00		784.00	986.00
21160	Lefort iii w/fhd w/lefort i		2.50		1.00	2.50		844.00	1121.00
21172	Reconstruct orbit/forehead		1.50		1.00	1.50		474.00	641.00
21175	Reconstruct orbit/forehead		1.00		1.00	2.00		767.00	731.00
21179	Reconstruct entire forehead				1.00	2.00		412.00	590.00
21180	Reconstruct entire forehead				1.00	2.00		492.00	670.00
21181	Contour cranial bone lesion	1.00			1.00			338.00	396.00
21182	Reconstruct cranial bone		1.00		1.00	2.00		856.00	801.00
21183	Reconstruct cranial bone		2.00		1.00	2.00		669.00	891.00
21184	Reconstruct cranial bone		2.00		1.00	2.00		774.00	996.00
22102	Remove part lumbar vertebra	3.00			1.00			392.00	387.00
22310	Closed tx vert fx w/o manj	3.50			1.00			167.00	236.00
28122	Partial removal of foot bone				1.00			230.00	249.00
33470	Revision of pulmonary valve	1.50			1.00	3.50		890.00	769.00
33471	Valvotomy pulmonary valve	4.00			1.00	1.00		603.00	572.00
33476	Revision of heart chamber				1.00	5.00		725.00	859.00
33478	Revision of heart chamber				1.00	5.00		740.00	882.00
33610	Repair by enlargement	7.00			1.00			770.00	648.00
33720	Repair of heart defect				1.00	4.00		633.00	770.00
33737	Revision of heart chamber	2.00			1.00	3.00		603.00	706.00
33755	Major vessel shunt	1.50			1.00	3.50		680.00	750.00
33762	Major vessel shunt	1.50			1.00	3.50		740.00	755.00
33766	Major vessel shunt	1.50			1.00	3.50		740.00	756.00
33775	Repair great vessels defect	0.50			1.00	6.50		860.00	1043.00
33776	Repair great vessels defect	1.50			1.00	6.50		950.00	1096.00
33777	Repair great vessels defect	3.50			1.00	4.50		950.00	993.00
33813	Repair septal defect	1.00			1.00	3.00		603.00	664.00
33814	Repair septal defect				1.00	5.00		710.00	838.00
33822	Revise major vessel				1.00	2.00		430.00	463.00
50360	Transplantation of kidney	1.00	2.00	2.00	1.00			664.00	774.00
61556	Incise skull/sutures	3.00	3.00	1.00	1.00			749.00	692.00
61558	Excision of skull/sutures	5.00			1.00			669.00	661.00
61559	Excision of skull/sutures	4.00			1.00			662.00	665.00
61563	Excision of skull tumor	1.00	2.00	1.00	1.00			762.00	656.00
61564	Excision of skull tumor	4.00			1.00			629.00	623.00
61580	Craniofacial approach skull		3.00	4.00	1.00	1.00		1313.30	1078.30
61581	Craniofacial approach skull	1.00	1.00	5.00	1.00	1.00		1419.40	1214.40
61582	Craniofacial approach skull	4.00	3.00	1.00	1.00	1.00		1185.30	1010.30
61583	Craniofacial approach skull	8.00		1.00	1.00	1.00		1100.40	906.40
61584	Orbitocranial approach/skull	2.00	3.00	2.00	1.00	1.00		1066.40	842.40
61585	Orbitocranial approach/skull	1.00	3.00	3.00	1.00	2.00		1377.70	1101.70
61590	Infratemporal approach/skull	1.00		7.00	1.00	2.00		1732.40	1418.40
61591	Infratemporal approach/skull	3.00	4.00		1.00	2.00		1478.85	1254.85
61592	Orbitocranial approach/skull	1.00	3.00	2.00	1.00	2.00		1256.80	1002.80
61595	Transtemporal approach/skull		3.00	4.00	1.00	1.00		1312.80	1077.80

TABLE 11—PROPOSED WORK TIME CHANGES IN SELECTED GLOBAL SURGICAL PACKAGE VISITS—Continued

CPT code	Short descriptor	Visits included in Global Package						CY 2014 time	CY 2015 time
		99231	99232	99233	99238	99291	99292		
61596	Transcochlear approach/skull	1.00	4.00	3.00	1.00	1.00		1442.30	1188.30
61597	Transcondylar approach/skull	5.00	2.00	1.00	1.00	2.00		1284.40	1041.40
61598	Transpetrosal approach/skull	2.00	3.00	1.00	1.00	2.00		1253.10	1048.10
61600	Resect/excise cranial lesion			6.00	1.00	1.00		1328.40	1101.40
61601	Resect/excise cranial lesion	2.00	2.00	2.00	1.00	2.00		1078.90	854.90
61605	Resect/excise cranial lesion	3.00	2.00	1.00	1.00	2.00		1238.60	1052.60
61606	Resect/excise cranial lesion	3.00	3.00	1.00	1.00	2.00		1161.90	926.90
61607	Resect/excise cranial lesion		1.00	6.00	1.00	2.00		1526.20	1201.20
61608	Resect/excise cranial lesion	3.00	3.00	2.00	1.00	2.00		1326.00	1042.00
61613	Remove aneurysm sinus	1.00		6.00	1.00	2.00		1416.00	1102.00
61615	Resect/excise lesion skull	2.00	4.00	2.00	1.00	1.00		1327.20	1092.20
61616	Resect/excise lesion skull	5.00	2.00	1.00	1.00	2.00		1329.80	1116.80
61618	Repair dura		1.00	2.00	1.00			647.10	573.10
61619	Repair dura	1.00	2.00	1.00	1.00			683.60	587.60
62115	Reduction of skull defect	4.50			1.00			672.00	678.00
62116	Reduction of skull defect	1.00	2.00	1.00	1.00			737.00	616.00
62117	Reduction of skull defect		2.00	2.00	1.00			854.00	714.00
62120	Repair skull cavity lesion	3.00			1.00			512.00	523.00

6. 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.

It appears that practice patterns for endoscopic procedures are changing, and anesthesia is increasingly being separately reported for these procedures. For example, one study shows 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 shows that a similar pattern is occurring in the Medicare program. We find 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 shows that this rate is as high as 80 percent.

Our data clearly indicate that moderate sedation is no longer typical for all of the procedures listed in CPT's Appendix G, and, in fact, the data suggest that the percent of cases in which it is used is declining. For many of these procedures in Appendix G, moderate sedation continues to be furnished. The trend away from the use of moderate sedation toward a separately billed anesthesia service is not universal. It differs by the class of procedures, sometimes at the procedure code level, and is one that continues to evolve over time. Due to the changing nature of medical practice in this area, we are 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 are seeking public comment on approaches to address the appropriate valuation of these services. Specifically, we are 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 request 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 note 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. In the CY 2015 PFS final rule with comment period, we will address these interim final values, and we anticipate establishing CY 2015 inputs for the lower gastrointestinal procedures, many of which are also listed in Appendix G. It is our expectation that we will not 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 this proposed rule on the overall valuation of Appendix G codes.

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

a. General Discussion

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 parallels the process used in the CY 2010 update. The calculation requires 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 must be weighted geographically and by specialty. Accordingly, the proposed MP RVUs are 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 MP premium data primarily from state departments of insurance. 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). Given that the national average premium amount for registered dietitians, physician assistants and optometry is below the national average premium amount for allergy and immunology, we crosswalked these specialties to allergy and immunology, the specialty with the lowest premiums for which we had sufficient and reliable data.

For the proposed CY 2015 MP RVU update, sufficient and reliable premium data were available for 41 specialty types, which we used to develop specialty-specific malpractice risk factors. (See Table 13 for a list of these specialties.)

For specialties with insufficient or unreliable premium data, we assigned the premium amounts of a similar specialty type. These specialties and the specialty data that we propose to use are shown in Table 12.

TABLE 12—CROSSWALK OF SPECIALTIES TO SIMILAR SPECIALTIES

Specialty code	Medicare specialty name	Crosswalk specialty code	Crosswalk specialty
09	Interventional Pain Management	05	Anesthesiology.
12	Osteopathic Manipulative Medicine	03	Allergy Immunology.
15	Speech Language Pathology	03	Allergy Immunology.
17	Hospice and Palliative Care	03	Allergy Immunology.
19	Oral Surgery (dental only)	24	Plastic and Reconstructive Surgery.
21	Cardiac Electrophysiology	06	Cardiology.
23	Sports Medicine	01	General Practice.
27	Geriatric Psychiatry	26	Psychiatry.
32	Anesthesiologist Assistant	05	Anesthesiology.
35	Chiropractic	03	Allergy Immunology.
41	Optometry	03	Allergy Immunology.
42	Certified Nurse Midwife	16	Obstetrics Gynecology.
43	Certified Registered Nurse Anesthetist	05	Anesthesiology.
50	Nurse Practitioner	01	General Practice.
60	Public Health or Welfare Agency	03	Allergy Immunology.
62	Psychologist	03	Allergy Immunology.
64	Audiologist	03	Allergy Immunology.
65	Physical Therapist	03	Allergy Immunology.
67	Occupational Therapist	03	Allergy Immunology.
68	Clinical Psychologist	03	Allergy Immunology.
71	Registered Dietitian/Nutrition Professional	03	Allergy Immunology.
72	Pain Management	05	Anesthesiology.
76	Peripheral Vascular Disease	77	Vascular Surgery.
79	Addiction Medicine	03	Allergy Immunology.
80	Licensed Clinical Social Worker	03	Allergy Immunology.
83	Hematology/Oncology	90	Medical Oncology.
85	Maxillofacial Surgery	24	Plastic and Reconstructive Surgery.
86	Neuropsychiatry	26	Psychiatry.
89	Certified Clinical Nurse Specialist	01	General Practice.
91	Surgical Oncology	02	General Surgery.
94	Interventional Radiology	30	Diagnostic Radiology.
97	Physician Assistant	03	Allergy Immunology.
98	Gynecological/Oncology	16	Obstetrics Gynecology.
99	Unknown Physician Specialty	01	General Practice.
C0	Sleep Medicine	01	General Practice.

b. Steps for Calculating Proposed Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2010 final rule with comment period (74 FR 61758). The specialty-weighted approach bases the MP RVUs for a given service upon a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are accounted for in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

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

Insurance rating area MP premiums for each specialty are mapped to the

county level. The specialty premium for each county is then multiplied by the total county RVUs for that specialty (from the Medicare claims data for CY 2013). The product of the MP premiums and total county RVUs is then summed across all counties for each specialty and then divided by total national RVUs for the specialty. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

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

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. To account for the presence of different classes in the MP premium data and the task of mapping these premiums to procedures, we calculated distinct risk factors for surgical, surgical with obstetrics, and nonsurgical procedures. However, the availability of data by surgery and nonsurgery varied across specialties. Consistent with the CY 2010 MP RVU update, because no single approach accurately addressed the variability in premium classes among specialties, we employed several methods for calculating average premiums by specialty. These methods are discussed below.

(a) *Substantial Data for Each Class:* For 13 out of 41 specialties, we determined that there was sufficient data for surgery and nonsurgery premiums, as well as sufficient differences in rates between classes. These specialties are listed in Table 13. Therefore, we calculated a national average surgical premium and nonsurgical premium.

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

(c) *Unspecified Dominates:* Many MP rate filings did not include surgery or nonsurgery classes for some specialties; we refer to these instances as unspecified MP rates. For 7 specialty types (listed in Table 13), we selected the unspecified premium as the premium information to use for the specialty. For these specialties, at least 35 states (and as many as 48 states) had MP premium amounts that were not identified as surgery or nonsurgery in rate filings for the specialty.

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

The four methods for calculating premiums by specialty type are summarized in Table 13. (See Table 14: ''Risk Factors by Specialty Type'' for the specialty names associated with the specialty codes listed in Table 13.)

TABLE 13—PROPOSED PREMIUM CALCULATION APPROACH BY SPECIALTY TYPE

Method	Medicare specialty codes
(a) Substantial Data for Each Class (13)	01, 04, 06, 07, 08 (non-OB), 10, 13, 18, 34, 38, 39, 46, 93
(b) Major Surgery Dominates (9)	02, 14, 20, 24, 28, 33, 40, 77, 78
(c) Unspecified Dominates (7)	03, 05, 16 (non-OB), 25, 26, 36, 81
(d) Blend All Available (12)	11, 22, 29, 30, 37, 44, 48, 66, 82, 84, 90, 92

(e) *Premium Calculation for Neurosurgery:* For neurosurgery, premium data were available from 24 states; therefore, we did not have sufficient data to calculate a national average premium amount for neurosurgery. As explained above, we typically crosswalk a specialty with insufficient premium data (less than 35 states) to a similar specialty for which we have sufficient data, conceptually or by reported premiums. We considered cross-walking neurosurgery directly to the national average premium for a similar specialty that had sufficient data such as neurology or to another surgical specialty. We did not crosswalk neurosurgery directly to another surgical specialty because no other surgical specialty had similar premium values reported in the rate filings. For instance, the surgical premium for neurosurgery is $123,400 while the surgical premium for the next highest surgical specialty (surgical oncology) is $59,808. We also did not crosswalk neurosurgery directly to neurology because the rate filings for neurology include substantial premium data for both surgery and non-surgery while the rate filings for neurosurgery are dominated by major surgery premiums. We do not believe that it would be appropriate to assign non-surgical premiums reported for neurology to neurosurgery.

However, the national average *surgical* premium amount for neurology ($96,970) and the surgical premium amount for neurosurgery are similar. Therefore, we blended the surgical premium data for neurology and neurosurgery instead of crosswalking directly to neurology or directly to another surgical specialty. In other words, we calculated a combined national average surgical premium for neurosurgery and neurology. The reasons as to why we are proposing to blend surgical premiums for neurology and neurosurgery, instead of crosswalking neurosurgery directly to neurology or directly to another surgical specialty, are further explained below.

- The rate filings for neurosurgery are dominated by major surgery premiums.
- The rate filings identifying nonsurgical premiums for neurosurgery are sparse.
- The rate filings for neurology include substantial premium data for both surgery and nonsurgery.

• Neurology is similar to neurosurgery both conceptually and by reported surgical premium amounts.

• Surgical premiums from the rate filings for other surgical specialties are lower than for neurosurgery and neurology.

Given that the rate filings for neurosurgery are dominated by major surgical premiums and that surgical premium amounts for neurology are similar to neurosurgery, we believe that combining the surgical premium data for neurosurgery and neurology is a better representation of the MP premium amounts paid by neurosurgeons than crosswalking neurosurgery directly to neurology or to another surgical specialty.

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

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty risk factor. These risk factors are an index calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which we had sufficient and reliable data, allergy and immunology. For specialties with sufficient surgical and nonsurgical premium data, we calculated both a surgical and nonsurgical risk factor. For specialties with rate filings that distinguished surgical premiums with obstetrics from those without, we calculated a separate surgical with obstetrics risk factor. For all other specialties we calculated a single risk factor and applied the specialty risk factor to both surgery and nonsurgery services.

We note that for determining the risk factor for suppliers of TC-only services, we were not able to obtain more recent premium data than what was used for the CY 2010 update. Therefore, we updated the premium data for IDTFs that we used in the CY 2010 update. These data were obtained from a survey conducted by the Radiology Business Management Association (RBMA) in 2009. We updated the RBMA survey data by the change in non-surgical premiums for all specialty types since the previous MP RVU update and calculated an updated TC specialty risk factor. We applied the updated TC specialty risk factor to suppliers of TC-only services. Table 14 shows the risk factors by specialty type.

TABLE 14—RISK FACTORS BY SPECIALTY TYPE

Specialty code	Medicare specialty name	Non-surgical risk factor	Surgical risk factor
01	General Practice	1.83	4.11
02	General Surgery		7.30
03	Allergy Immunology	1.00	1.00
04	Otolaryngology	1.95	4.47
05	Anesthesiology	2.42	2.42
06	Cardiology	2.11	7.10
07	Dermatology	1.25	4.11
08	Family Practice	1.77	4.18
08 OB	Family Practice w/OB		3.95
09	Interventional Pain Management	2.42	2.42
10	Gastroenterology	2.16	4.45
11	Internal Medicine	2.07	2.07
12	Osteopathic Manipulative Medicine	1.00	1.00
13	Neurology	2.59	13.04
14	Neurosurgery		13.04
15	Speech Language Pathology	1.00	1.00
16	Obstetrics Gynecology	3.80	3.80
16 OB	Obstetrics Gynecology w/OB		8.05
17	Hospice and Palliative Care	1.00	1.00
18	Ophthalmology	1.22	2.21
19	Oral Surgery (dental only)		5.11
20	Orthopedic Surgery		6.38
21	Cardiac Electrophysiology	2.11	7.10
22	Pathology	1.79	1.79
23	Sports Medicine	1.83	4.11
24	Plastic and Reconstructive Surgery		5.11
25	Physical Medicine and Rehabilitation	1.39	1.39
26	Psychiatry	1.13	1.13
27	Geriatric Psychiatry	1.13	1.13
28	Colorectal Surgery (formerly Proctology)		4.08
29	Pulmonary Disease	2.33	2.33
30	Diagnostic Radiology	2.99	2.99
32	Anesthesiologist Assistant	2.42	2.42
33	Thoracic Surgery		7.27
34	Urology	1.61	3.39
35	Chiropractic	1.00	1.00
36	Nuclear Medicine	1.41	1.41
37	Pediatric Medicine	1.82	1.82
38	Geriatric Medicine	1.78	4.83
39	Nephrology	1.71	4.27
40	Hand Surgery		4.71
41	Optometry	1.00	1.00
42	Certified Nurse Midwife	3.80	3.80
42 OB	Certified Nurse Midwife w/OB		8.05
43	Certified Registered Nurse Anesthetist (CRNA)	2.42	2.42
44	Infectious Disease	2.41	2.41
45	Mammography Screening Center	0.90	

TABLE 14—RISK FACTORS BY SPECIALTY TYPE—Continued

Specialty code	Medicare specialty name	Non-surgical risk factor	Surgical risk factor
46	Endocrinology	1.65	4.23
47	Independent Diagnostic Testing Facility	0.90	
48	Podiatry	2.22	2.22
50	Nurse Practitioner	1.83	4.11
60	Public Health or Welfare Agency	1.00	1.00
62	Psychologist	1.00	1.00
63	Portable X-Ray Supplier	0.90	
64	Audiologist	1.00	1.00
65	Physical Therapist	1.00	1.00
66	Rheumatology	1.77	1.77
67	Occupational Therapist	1.00	1.00
68	Clinical Psychologist	1.00	1.00
69	Clinical Laboratory	0.90	
71	Registered Dietitian/Nutrition Professional	1.00	1.00
72	Pain Management	2.42	2.42
74	Radiation Therapy Center	0.90	
75	Slide Preparation Facilities	0.90	
76	Peripheral Vascular Disease		7.19
77	Vascular Surgery		7.19
78	Cardiac Surgery		7.23
79	Addiction Medicine	1.00	1.00
80	Licensed Clinical Social Worker	1.00	1.00
81	Critical Care (Intensivists)	2.83	2.83
82	Hematology	1.81	1.81
83	Hematology/Oncology	1.89	1.89
84	Preventive Medicine	1.44	1.44
85	Maxillofacial Surgery		5.11
86	Neuropsychiatry	1.13	1.13
89	Certified Clinical Nurse Specialist	1.83	4.11
90	Medical Oncology	1.89	1.89
91	Surgical Oncology		7.30
92	Radiation Oncology	2.36	2.36
93	Emergency Medicine	3.29	5.17
94	Interventional Radiology	2.99	2.99
97	Physician Assistant	1.00	1.00
98	Gynecological/Oncology	3.80	3.80
98 OB	Gynecological/Oncology w/OB		8.05
99	Unknown Physician Specialty	1.83	4.11
C0	Sleep Medicine	1.83	4.11
TC	IDTFs (TC only)	0.90	

(a) Invasive Cardiology: Consistent with the previous MP RVU update, we continued to classify invasive cardiology services (cardiac catheterizations and angioplasties) that are outside of the surgical HCPCS code range as surgery for purposes of assigning specialty-specific risk factors. We note that since the previous MP RVU update some invasive cardiology service HCPCS codes have been revised. Therefore, we modified the list of invasive cardiology services outside the surgical HCPCS code range that are to be considered surgery in order to correspond conceptually to the list of service codes used for the CY 2010 MP RVU update. We continue to believe that the malpractice risk for cardiac catheterization and angioplasty services are more similar to the risk of surgical procedures than most nonsurgical service codes. As such, we applied the higher cardiology surgical risk factor to cardiology catheterization and angioplasty services.

For the CY 2015 MP RVU update, we examined the possibility of classifying injection procedures used in conjunction with cardiac catheterization as surgery (for purposes of assigning service specific risk factors). After careful consideration, we believe that injection procedures, when furnished in conjunction with cardiac catheterization, are more akin to the malpractice risk of surgical procedures than most non-surgical services. Therefore we applied the surgical risk factor to injection procedures used in conjunction with cardiac catheterization. Table 15 shows the invasive cardiology services and injection services furnished in conjunction with cardiac catheterization to be considered as surgery for purposes of assigning specialty-specific risk factors.

TABLE 15—SERVICES OUTSIDE OF SURGICAL HCPCS CODE RANGE CONSIDERED SURGERY

HCPCS code	Short descriptor
92920	Prq cardiac angioplast 1 art.
92921	Prq cardiac angio addl art.
92924	Prq card angio/athrect 1 art.
92925	Prq card angio/athrect addl.
92928	Prq card stent w/angio 1 vsl.
92929	Prq card stent w/angio addl.
92933	Prq card stent/ath/angio.
92934	Prq card stent/ath/angio.
92937	Prq revasc byp graft 1 vsl.
92938	Prq revasc byp graft addl.
92941	Prq card revasc mi 1 vsl.
92943	Prq card revasc chronic 1vsl.
92944	Prq card revasc chronic addl.
92970	Cardioassist internal.
92971	Cardioassist external.
92973	Prq coronary mech thrombect.
92974	Cath place cardio brachytx.
92975	Dissolve clot heart vessel.
92977	Dissolve clot heart vessel.
92978	Intravasc us heart add-on.

TABLE 15—SERVICES OUTSIDE OF SURGICAL HCPCS CODE RANGE CONSIDERED SURGERY—Continued

HCPCS code	Short descriptor
92979	Intravasc us heart add-on.
93451	Right heart cath.
93452	Left hrt cath w/ventrclgrphy.
93453	R&l hrt cath w/ventriclgrphy.
93454	Coronary artery angio s&i.
93455	Coronary art/grft angio s&i.
93456	R hrt coronary artery angio.
93457	R hrt art/grft angio.
93458	L hrt artery/ventricle angio.
93459	L hrt art/grft angio.
93460	R&l hrt art/ventricle angio.
93461	R&l hrt art/ventricle angio.
93462	L hrt cath trnsptl puncture.
93503	Insert/place heart catheter.
93505	Biopsy of heart lining.
93530	Rt heart cath congenital.
93531	R & l heart cath congenital.
93532	R & l heart cath congenital.
93533	R & l heart cath congenital.
93580	Transcath closure of asd.
93581	Transcath closure of vsd.
93582	Perq transcath closure pda.
93583	Perq transcath septal reduxn.
93600	Bundle of his recording.
93602	Intra-atrial recording.
93603	Right ventricular recording.
93609	Map tachycardia add-on.
93610	Intra-atrial pacing.
93612	Intraventricular pacing.
93613	Electrophys map 3d add-on.
93618	Heart rhythm pacing.
93619	Electrophysiology evaluation.
93620	Electrophysiology evaluation.
93621	Electrophysiology evaluation.
93622	Electrophysiology evaluation.
93623	Stimulation pacing heart.
93624	Electrophysiologic study.
93631	Heart pacing mapping.
93640	Evaluation heart device.
93641	Electrophysiology evaluation.
93642	Electrophysiology evaluation.
93650	Ablate heart dysrhythm focus.
93653	Ep & ablate supravent arrhyt.
93654	Ep & ablate ventric tachy.
93655	Ablate arrhythmia add on.
93656	Tx atrial fib pulm vein isol.
93657	Tx l/r atrial fib addl.
93563	Inject congenital card cath.
93564	Inject hrt congntl art/grft.
93565	Inject l ventr/atrial angio.
93566	Inject r ventr/atrial angio.
93567	Inject suprvlv aortography.
93568	Inject pulm art hrt cath.
93571	Heart flow reserve measure.
93572	Heart flow reserve measure.

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

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

(a) *Low volume service codes:* As discussed previously in this section, service-specific MP RVUs are determined based on the weighted average risk factor(s) of the specialties that furnish the service. For rarely-billed Medicare services (that is, when CY 2013 claims data reflected allowed services of less than 100), we used only the risk factor of the dominant specialty as reflected in our claims data. Approximately 2,000 services met the criteria for ''low volume.'' The dominant specialty for each ''low volume'' service was also determined from CY 2013 Medicare claims data. We continue to believe that a balanced approach between including all of the specialties in our claims data and the application of the dominant specialty for each low volume service is the most appropriate approach to the development of malpractice RVUs.

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. The current resource-based MP RVUs and the proposed resource-based MP RVUs were constructed using different malpractice premium data. Thus, the last step is to adjust for budget neutrality by rescaling the proposed MP RVUs so that the total proposed resource-based MP RVUs equal the total current resource-based MP RVUs.

The proposed resource-based MP RVUs are shown in Addendum B, which is available on the CMS Web site under the supporting documents section of the CY 2015 PFS rule at *http://www.cms.gov/PhysicianFeeSched/.* These values have been adjusted for budget neutrality on the basis of the most recent 2013 utilization data available. We will make a final budget neutrality adjustment in the final rule on the basis of the available 2013 utilization data at that time. We do not believe, however, that the final values will change significantly from the proposed values as a result of the final budget-neutrality adjustment.

Because of the differences in the sizes of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type can be found in section VI. of this proposed rule.

Additional information on our proposed methodology for updating the MP RVUs may be found in our contractor's report, ''Report on the CY 2015 Update of the Malpractice RVUs,'' which is available on the CMS Web site. It is located under the supporting documents section of the CY 2015 PFS proposed rule located at *http://www.cms.gov/PhysicianFeeSched/.*

3. MP RVU Update for Anesthesia Services

Since payment for anesthesia services under the PFS is based upon a separate fee schedule, routine updates must be calculated in a different way than those for services for which payment is calculated based upon work, PE and MP RVUs. To apply certain updates to the anesthesia fee schedule, we usually develop proxy RVUs for individual anesthesia services. However, because work RVUs are integral to the MP RVU methodology and anesthesia services do not have work RVUs, the MP update process for anesthesia services is more complex than for services with work RVUs and clinical labor inputs. Notwithstanding these challenges, we believe that payment rates for anesthesia should reflect relative MP resource costs, including updates to reflect changes over time, as do other PFS payment rates. We are not proposing to include such an adjustment at this time because we believe it would be helpful to receive input from stakeholders on how we could address these challenges and develop a proposal to appropriately update the MP resource costs for anesthesia through future rulemaking. Therefore, we intend to propose an anesthesia adjustment for MP in the CY 2016 PFS proposed rule and are seeking comment in this rule about how to best do so.

An example of one possible approach would be to calculate imputed work RVUs and MP RVUs for the anesthesia fee schedule services using the work, PE, and MP shares of the anesthesia conversion factor. To reflect differences in the complexity and risk between

anesthesia fee schedule services we would then multiply the service-specific risk factor for each anesthesia fee schedule service by the imputed proxy work RVUs (both CY 2015 and Cy 2016 would be based on the same work RVUs) developed for each anesthesia service to determine updated proxy MP RVUs for the CY 2016 year. The aggregate difference between the imputed MP RVUs for CY 2015 the proxy MP RVUs for CY 2016 (both based on the same work RVUs) would be applied to the portion of the anesthesia conversion factor attributable to MP. However, we believe there may be drawbacks to this approach since it relies heavily on the proxy work and MP RVUs for individual anesthesia services. We are requesting public comments on this approach specifically, as well as comments on alternative approaches or methods for updating MP for services paid on the anesthesia fee schedule.

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 ½ 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, CY 2011 and CY 2012, we phased in ½ 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. 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 have been 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. See Addenda D and E for the CY 2015 GPCIs and summarized GAFs.

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. 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

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 above, 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.

Table 16 illustrates the percentage change in GPCI values and summarized GAF for the Virgin Islands payment locality resulting from using BLS OES wage data to calculate the work GPCI and PE GPCI.

TABLE 16—IMPACT OF USING TERRITORY-LEVEL VIRGIN ISLANDS DATA ON GPCI VALUES FOR THE VIRGIN ISLANDS PAYMENT LOCALITY

GPCI/GAF	1/1/2015 through 3/31/2015 (with 1.0 work GPCI floor)			4/1/2015 through 12/31/2015 (without 1.0 work GPCI floor)		
	Existing CY 2015 GPCI values*	Proposed CY 2015 GPCI values	Percent change	Existing CY 2015 GPCI values*	Proposed CY 2015 GPCI values	Percent change
Work GPCI	1.000	1.000	0.00%	0.998	0.975	−2.30
PE GPCI	1.005	0.960	−4.48%	1.005	0.960	−4.48
MP GPCI	0.996	0.996	0.00%	0.996	0.996	0.00
GAF	1.002	0.982	−2.00%	1.001	0.969	−3.20

*CY 2015 GPCIs and GAF reflect CMS OACT BN adjustment.

Using aggregate territory-level BLS OES wage data results 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, there is no change in the MP GPCI. We propose to use aggregate BLS OES wage data to calculate the work GPCI and employee wage component of the PE GPCI for the Virgin Islands payment locality beginning for CY 2015, and for future GPCI updates. We are specifically requesting public comments on this proposal. Additional information on our proposal to calculate 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 Web site. It is located under the supporting documents section of the CY 2015 PFS proposed rule located at *http://www.cms.gov/PhysicianFeeSched/.*

E. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Generally, for Medicare payments to be made for telehealth services under the PFS several conditions must be met. Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other 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 for 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 provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process in the CY 2003 PFS final rule with comment period (67 FR 79988) for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act.

As specified in regulations 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 the telehealth service provision is 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/hosptialcommunication.*

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare 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 are defined as ''one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system,'' are paid under the PFS for serving as an originating site for telehealth services. The statute specifies both the types of entities that can serve as originating sites and geographic qualifications for originating sites. With regard to geographic qualifications, our regulations at § 410.78 (b)(4) limit originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical areas (MSAs). Historically, we have defined rural HPSAs to be those located outside of, MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining ''rural'' to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of ''rural'' for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a Web site tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see the CMS Web site at *www.cms.gov/teleheath/.*

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

Effective January 1, 2014, we also changed our policy so that geographic 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. We assign any qualifying request to make additions to the list of telehealth services to one of two categories. In the November 28, 2011 **Federal Register** (76 FR 73102), we finalized revisions to criteria that we use to review requests in the second category. 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 Web site at *www.cms.gov/teleheath/.* Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 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 Web site 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 proposed rule (76 FR 42826), we believe that the category 1 criteria not only streamline our review process for publically 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 are not proposing 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 furnished without the patient being present in the same location. (Note: Sometimes an entirely different code may be 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.) 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. It is not necessary to consider including the PC of these services on the telehealth list for these services to be covered when furnished remotely. Moreover, when these 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, telehealth restrictions 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 are not proposing 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 are not proposing 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 62.5 percent outpatient mental health treatment limitation, in effect since the inception of the Medicare program, be reduced over four years. This limitation limits the percentage of allowed charges that the Medicare program paid for mental health treatment services, thus creating a larger share of beneficiary coinsurance for these services than other Medicare PFS services. Effective January 1, 2014, the limitation percentage is 100 percent, of which Medicare pays 80 percent and the beneficiary pays 20 percent, resulting in the same beneficiary cost sharing as 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 Telehealth 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 are proposing 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 proposed rule, 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 also amended the regulation at § 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 many other mechanisms by which we can make the public aware of the list of Medicare telehealth services for each year, we are proposing to revise § 410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth. 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 are also proposing to revise § 410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS Web site.

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 its inception 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 potentially misvalued code initiative under 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 in order 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 asserted 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 Web site 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. They believe 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 range 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 as 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 gone down, 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 proposed rule for a discussion of proposed valuation of these epidural injection codes for CY 2015).

3. Alternatives to the Current Process

Although we continue to believe the existing process for new, revised and potentially misvalued codes is an appropriate one given the incongruity between our rulemaking schedule and the CPT and RUC schedules, given our heightened review of the RUC recommendations and the increased concerns expressed by some stakeholders, we believe that an assessment of our process for valuing these codes is warranted. To that end, we have 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 have 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.

A discussion of each of these alternatives 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 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, 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 a 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 in order 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) 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 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 Web site 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 are proposing 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 propose 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. For the CY 2016 rulemaking process, we would include in the proposed rule proposed values for all services for which we have RUC recommendations by January 15, 2015.

For those codes for which we do not receive the RUC recommendations by January 15th of a year, we would 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. 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 propose 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 practicable 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 describe services which 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 need to 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 propose to modify the regulation at § 414.24 to codify the process described above.

We recognize that the use of G-codes, especially if there are many of them in a given year, may place an administrative burden on those who bill

for services under the PFS. We also recognize that, to the extent we do not receive RUC recommendations in time to include proposed values in the proposed rule, the most updated version of some CPT codes would not be used by the Medicare program for the first year. The AMA has been working to develop timeframes that would allow a much greater 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 hopeful that if this proposal is adopted the CPT Editorial Panel and the RUC ultimately 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.

As discussed previously, the work of the AMA through the CPT Editorial Panel and the RUC are critical elements in the appropriate valuation of services under the PFS. We have proposed implementation of the revised CMS process for establishing values for new, revised, and potentially misvalued codes for CY 2016; but would consider alternative implementation dates to allow time for the CPT Editorial Panel and the RUC to adjust their schedules to avoid the necessity to use G-codes.

With regard to this proposal, we would be specifically interested in 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?

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 consider changes to the processes for valuing codes, we are reassessing the role that the refinement panel process plays in the code valuation process. As we note in the discussion above, 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. 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 a very few codes that describe totally new services. Thus, we are proposing to eliminate the refinement panel process. By using the proposed process for new, revised, and potentially misvalued codes, we believe that the consideration of additional clinical information and any other issues associated with the CMS proposed values could be addressed through the notice and public 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 note that an increasing number of requests for refinement do not include new clinical information that was not available at the time of the RUC meeting that would justify a change in the work RVUs, in accordance with the current requirements for refinement. Thus, we do 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.

G. 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 Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site 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 Web site at *http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/*).
- The Primary Care Incentive Payment (PCIP) Program (described on the CMS Web site 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 Web site 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 Web site at *http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/FQHC_APCP_Demo_FAQsOct2011.pdf* and the Innovation Center's Web site at *www.innovations.cms.gov/initiatives/FQHCs/index.html*).

• The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's Web site 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 Web site 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 two or more chronic conditions. (See 78 FR 74414 for a more complete description of the beneficiaries for whom this service may be billed.) In the CY 2014 PFS final rule with comment period, we indicated that, to recognize the additional resources required to provide 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 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 used the work RVU and work time associated with the non-face-to-face portion of CPT code 99495 as a foundation to determine our proposed values for CCM services. Specifically, we are proposing 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 are proposing 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. The work time file associated with this PFS proposed rule is available on the CMS Web site in the Downloads section for the CY 2015 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For direct PE inputs, we are proposing 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 believe that many aspects of this service will be provided by clinical staff, and thus, clinical staff will be involved in the typical service for the full 20 minutes. The proposed CY 2015 direct PE input database reflects this input and is available on the CMS Web site 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 proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from using these inputs to establish PE RVUs.

The proposed MP RVU was calculated using the weighted risk factors for the specialties that we believe will furnish this service. We believe this malpractice risk factor appropriately reflects the relative malpractice risk associated with furnishing CCM services. The MP RVU included in Addendum B of this proposed rule reflects the RVU that results from the application of this proposal.

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 (75 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 the availability to a beneficiary 24-hours-a-day, 7-days-a-week to address the patient's chronic care needs (78 FR 74426) that 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 patient'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 patients 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 this rule, we are proposing to revise the policy that we adopted in the CY 2014 PFS final rule with comment period, and to amend our regulations to codify the requirements for CCM services furnished incident to a practitioner's services. Specifically, we are proposing 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 are also proposing 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 requirements of the ''incident to'' regulations at § 410.26 are met.

We are proposing 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 patient'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'' under general supervision if the auxiliary personnel providing the services in conjunction with CCM services are clinical staff, and whether or not they are direct employees of the practitioner or practice billing for the service; but the clinical staff must meet the requirements for auxiliary personnel contained in § 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 are also proposing 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 patients. 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 are not proposing to extend this policy to the E/M service that is a required element of TCM. Rather, the required E/M service must still be furnished under direct supervision.

Therefore, we are proposing 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 documentation of services provided must be included in the medical record.

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 services required in order for a practitioner to bill Medicare for CCM services. 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 this 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, 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 had 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 already in place for health care practitioners and that will apply to those who furnish and bill for CCM services, we have decided not to propose an additional set of standards that must 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 have 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.

In one area—that of electronic health records—we are 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 beneficiary and among health care practitioners treating the beneficiary. As a part of the CY 2014 PFS final rule with comment period (78 FR 43338 through 43339), we specified that the electronic health record for a patient receiving CCM services should include a full list of problems, medications and medication allergies in order to inform the care plan, care coordination, and ongoing clinical care. Furthermore, those furnishing CCM services must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers as a part of managing health care transitions. We believe that if care is to be coordinated effectively, all communication must be timely, and it must include the information that each team member needs to know to furnish care that is congruent with a patient's needs and preferences. In addition, those furnishing CCM services need to establish reliable flows of information from emergency departments, hospitals, and providers of post-acute care services to track their CCM patients receiving care in those settings. Reliable information flow supports care transitions, and can be used to assess the need for modifications of the care plan that will reduce the risk of readmissions, increased morbidity, or mortality.

After gathering input from stakeholders, we believe that requiring those who furnish CCM services to utilize electronic health record technology that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology will ensure that practitioners have adequate capabilities to allow members of the interdisciplinary care team to have immediate access to the most updated information informing the care plan. Furthermore, we believe that requiring those that furnish CCM services to maintain and share an electronic care plan will alleviate the development of duplicative care plans or updates and the associated errors that can occur when care plans are not systematically reconciled. To ensure that practices offering CCM services meet these needs, we are proposing a new scope of service requirement for electronic care planning capabilities and electronic health records. Specifically, we are proposing that CCM services must be furnished with the use of an electronic health record or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers 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. To ensure all practices have adequate capabilities to meet electronic health record requirements, 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 electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. 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. For example, practitioners furnishing CCM services beginning in CY 2015 would be required to utilize an electronic health record certified to at least those 2014 Edition certification criteria. Given these certification criteria, 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)). When any of the CCM scope of service requirements include a reference to a health or medical record, a system meeting these requirements is required.

We believe this scope of service element will ensure that practitioners have adequate capabilities to fully

furnish CCM services, allow practitioners to innovate around the systems that they use to furnish these services, and avoid overburdening small practices. We believe that allowing flexibility as to how providers capture, update, and share care plan information is important at this stage given the maturity of current electronic health record 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 are seeking 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.

To assist stakeholders in commenting, we remind you of the elements of the current scope of service for CCM services that are required in order for a practitioner to bill Medicare for CCM services as finalized in the CY 2014 final rule with comment period. We would note that additional explanation of these elements can be found at 78 FR 74414 through 74428. The CCM service includes:

- Access to care management services 24-hours-a-day, 7-days-a-week, which means providing beneficiaries 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 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.
- Creation of a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care 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.
- Management of care transitions between and among health care providers and settings, including referrals to other clinicians, follow-up after a beneficiary visit to an emergency department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities.
- Coordination with home and community based clinical service providers as appropriate to support a beneficiary's 's psychosocial needs and functional deficits.
- Enhanced opportunities for a 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 remind stakeholders that in the CY 2014 final rule, we established particular billing requirements for CCM services that require the practitioner to:

- 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 patient's medical record that all of the CCM services were explained and offered to the patient, 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.
- Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of a 30-day period) and the effect of a revocation of the agreement on CCM services.
- Inform the beneficiary that only one practitioner can furnish and be paid for these services during the 30-day period.

With the addition of the electronic health record element that we are proposing, we believe that these elements of the scope of service for CCM services, when combined with other important federal health and safety regulations, provide sufficient assurance that Medicare beneficiaries receiving CCM services will receive appropriate services. However, we remain interested in receiving public feedback regarding any meaningful elements of the CCM service or beneficiary protections that may be missing from these scope of service elements and billing requirements. We encourage commenters, in recommending additional possible elements or safeguards, to provide as much specific detail as possible regarding their recommendations and how they can be applied to the broad complement of practitioners who may furnish CCM services under the PFS.

4. Payment of CCM Services in CMS Models and Demonstrations

As discussed above, several CMS models and demonstrations address payment for care management services. The Multi-payer Advanced Primary Care Practice Demonstration and the Comprehensive Primary Care 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 propose 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 propose 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 affecting existing models or demonstrations, we will address potential overlaps with CCM and seek to implement appropriate reimbursement policies. We welcome comments on this proposal. We also solicit 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.

H. Definition of Colorectal Cancer Screening Tests

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 standard of care for screening colonoscopies has been moderate sedation provided intravenously by the endoscopist, without resort to separately provided anesthesia.[1] Based on this standard of care, 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.[2] A 2010 study projected that the percentage of this class of procedures involving an anesthesia professional would grow to 53.4 percent by 2015.[3] These studies suggest that the prevailing standard of care for endoscopies in general and screening colonoscopies in particular is undergoing a transition, and that anesthesia separately provided by an anesthesia professional is becoming the prevalent practice. After reviewing these studies, we analyzed Medicare claims data and found that the same trend was observed in screening colonoscopies for Medicare beneficiaries. We found that in 53 percent of screening colonoscopies for which Medicare claims were submitted in 2013 a separate anesthesia claim was reported.

In light of these developments, we are concerned that the mere reference to ''screening colonoscopies'' in the definition of ''colorectal cancer screening tests'' has become inadequate. Indeed, we are 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 believe it is appropriate to revise the definition of ''colorectal cancer screening tests'' to adequately reflect these new patterns. Accordingly, we are proposing 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.

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 4104 of the Affordable Care Act, which amended section 1833(a)(1) of the Act to require 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 effectively waives any Part B coinsurance that would otherwise apply under section 1833(a)(1) of the Act 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 note 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). If adopted, we believe this proposal will encourage 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 are exercising our authority under section 1861(pp)(1)(D) of the Act to propose a revision to 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

[1] 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.

[2] 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.

[3] 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.

furnished in conjunction with a screening colonoscopy.

We note that, in implementing these proposed revisions to the regulations, it will 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. If we adopt this proposal in the final rule, we will 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 note that the valuation of colonoscopy codes, which include moderate sedation, will be subject to the same proposed review as other codes that include moderate sedation, as discussed in section II.B.6 of this proposed rule.

I. Payment of Secondary Interpretation of Images

In general, Medicare makes one payment for the professional component of an imaging service for each technical component service that is furnished. Section 100.1, Chapter 13, of the Medicare Claims Processing Manual (Pub. 100–04) explains this policy in the context of EKGs and X-rays furnished in an Emergency Room. The manual section discusses the distinction between a ''review'' of an X-ray or EKG for which payment is included in the payment for the emergency department E/M payment, and the ''interpretation and report'' of an X-ray or EKG which can be billed separately and includes a written report addressing ''the findings, relevant clinical issues, and comparative data (when available).'' The section makes clear that a ''professional component'' interpretation service should only be billed for a full interpretation and report. The manual section goes on to explain that, in general, Medicare pays for only one interpretation of an EKG or X-ray service furnished to an emergency room patient. However, Medicare can pay for a second interpretation (which is billed using modifier −77) under ''unusual circumstances (for which documentation is provided).'' For instance, if an emergency room physician conducts an interpretation, identifies a questionable finding, and believes another physician's expertise is needed, then a second claim for an interpretation can be paid when furnished, for example, by a radiologist. The second interpretation must directly contribute to the diagnosis and treatment of the individual patient (rather than serving as a quality control measure), and the second interpretation must also be accompanied by a written report.

While a separate payment for the professional component for a radiology service is contingent upon meeting the conditions described in this section, practitioners bill Medicare and are paid for reviews of radiology images in other ways. For instance, review of a patient's previous radiology images is included and paid as part of the review of previous documentation in conjunction with E/M services. Reviews of extensive documentation and efforts to obtain previous documentation including existing imaging studies are considerations in deciding the appropriate level of complexity for evaluation and management services.[4]

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. These advances offer new opportunities for physicians to reduce duplicative imaging, particularly with respect to high cost advanced diagnostic imaging modalities. For instance, a trauma patient transferred from a community hospital to a tertiary care center may arrive with high quality CT images sufficient to support an additional professional interpretation service. By accessing and utilizing these images to inform the diagnosis and record an interpretation in the medical record at the tertiary care facility, the provider and physicians may be able to avoid ordering substantially duplicative tests.

Questions have arisen as to whether and under what circumstances it would be appropriate for Medicare to permit payment under the PFS when physicians furnish subsequent interpretations of existing images, and whether uncertainty associated with payment for secondary interpretations inhibits physicians from seeking out, accessing, and utilizing existing images in cases where avoidance of a new study would result in savings to Medicare. We are seeking comment to assess whether there is an expanded set of circumstances under which it would be appropriate to allow more routine Medicare payment for a second professional component for radiology services, and whether such a policy would be likely to reduce the incidence of duplicative advanced imaging studies.

Specifically we are seeking comment on the following questions:

- For which radiology services are physicians currently conducting secondary interpretations, and what, if any, institutional policies are in place to determine when existing images are utilized? To what extent are physicians seeking payment for these secondary interpretations from Medicare or other payers?
- Should routine payment for secondary interpretations be restricted to certain high-cost advanced diagnostic imaging services, such as those defined as such under section 1834(e)(1)(B) of the Act, for example, diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography)?
- How should the value of routine secondary interpretations be determined? Is it appropriate to apply a modifier to current codes or are new HCPCS codes for secondary interpretations necessary?
- We believe most secondary interpretations would be likely to take place in the hospital setting. Are there other settings in which claims for secondary interpretations would be likely to reduce duplicative imaging services?
- Is there a limited time period within which an existing image should be considered adequate to support a secondary interpretation?
- Would allowing for more routine payment for secondary interpretations be likely to generate cost savings to Medicare by avoiding potentially duplicative imaging studies?
- What operational steps could Medicare take to ensure that any routine payment for secondary interpretations is limited to cases where a new imaging study has been averted while minimizing undue burden on providers or Part B contractors? For instance, steps might include restricting physicians' ability to refer multiple interpretations to another physician that is part of their network or group practice, requiring that physicians attach a physician's order for an averted imaging study to a claim for a secondary interpretation, or requiring physicians to identify the technical component of the existing image supporting the claim.

We seek comments on these questions, and welcome input on any additional considerations not mentioned here regarding the potential

[4] See, for example, 1997 Documentation Guidelines for Evaluation and Management Service, p. 45.

impact of allowing payment for secondary interpretation of images under other circumstances. Upon reviewing the comments received, we will consider whether any further action is appropriate, for instance, proposing under a future rulemaking to allow for payment of subsequent interpretations of advanced diagnostic images in lieu of duplicative studies.

J. Conditions Regarding Permissible Practice Types for Therapists in Private Practice

Section 1861(p) of the Act defines outpatient therapy services to include physical therapy, occupational therapy, and speech-language pathology 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 occupational therapy (OT), physical therapy (PT), and speech-language pathology (SLP), 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 recent review of these three sections of our regulations, we are 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 are proposing changes to the regulatory language to remove unnecessary distinctions and redundancies within the regulations for OT, PT, and SLP. We note that these proposed changes are for clarification only, and do not reflect any proposed 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 (for occupational therapists, physical therapists and speech-language pathologists), we propose to replace the regulatory text at § 410.59(c)(1)(ii)(A) through (E), § 410.60(c)(1)(ii)(A) though (E), and § 410.62(c)(1)(ii)(A) through (E).

K. Payments for Physicians and 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 are 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 physician or practitioner furnishes a complete assessment of the ESRD beneficiary, the MCP physician or 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 physician or 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. Stakeholders have recently brought this inconsistency to our attention. After reviewing this issue, we are proposing 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 physician or 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 physician or practitioner should bill for the full home dialysis MCP service. We believe that this proposed change to home dialysis (less than a full month) provides consistency with our policy for partial month scenarios pertaining to patients dialyzing in a dialysis center. 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.

III. Other Provisions of the Proposed Regulations

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) 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. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to these statutory requirements. (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.

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 Public Law 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. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements. (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.

B. Proposed 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 Proposed 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) and 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).

While 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, 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. Because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the CY 2014 PFS proposed rule, and thus, did not implement the changes to the OMB delineations under the ambulance fee schedule for CY 2014. We have reviewed our findings and impacts relating to the new OMB delineations, and find no compelling reason to further delay implementation. We believe it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible in order 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. 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 are proposing 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 the most recent version of the Goldsmith Modification. 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. These rural census tracts are considered rural areas under the ambulance fee schedule (see § 414.605). 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 Web site for a detailed listing of updated RUCA codes found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx.* The updated RUCA code definitions were introduced in late 2013 and are based on data from the 2010 decennial census and the 2006–10 American Community Survey. We are proposing 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. 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.

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 would 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 Web site: *ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf* for additional information. Consistent with the HRSA guidelines discussed above, we are proposing, 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. As discussed in the CY 2007 PFS final rule (71 FR 69715), 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 invite comments on this proposal.

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, 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). 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.

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)).

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. 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. The geographic designations for approximately 99.48 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes. There are a similar number of ZIP codes that would change from rural to urban (122, or 0.28 percent) and from urban to rural (100, or 0.23 percent). In general, it is 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. The state of Ohio would have the most ZIP codes changing from urban to rural with a total of 40, or 2.69 percent. 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. 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 are illustrated in Table 17.

TABLE 17—ZIP CODES ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State	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	0	0.00	0	0.00	854	100.00
AR	725	0	0.00	3	0.41	722	99.59
AS	1	0	0.00	0	0.00	1	100.00
AZ	569	0	0.00	0	0.00	569	100.00
CA	2723	0	0.00	0	0.00	2723	100.00
CO	677	0	0.00	0	0.00	677	100.00
CT	445	15	3.37	0	0.00	430	96.63
DC	301	0	0.00	0	0.00	301	100.00
DE	99	1	1.01	0	0.00	98	98.99
EK	63	0	0.00	0	0.00	63	100.00
EM	856	0	0.00	3	0.35	853	99.65
FL	1513	5	0.33	0	0.00	1508	99.67
FM	4	0	0.00	0	0.00	4	100.00
GA	1032	4	0.39	0	0.00	1028	99.61
GU	21	0	0.00	0	0.00	21	100.00
HI	143	0	0.00	0	0.00	143	100.00
IA	1080	5	0.46	0	0.00	1075	99.54
ID	335	0	0.00	0	0.00	335	100.00
IL	1628	0	0.00	0	0.00	1628	100.00
IN	1000	1	0.10	14	1.40	985	98.50
KY	1030	0	0.00	0	0.00	1030	100.00
LA	739	2	0.27	0	0.00	737	99.73
MA	751	0	0.00	4	0.53	747	99.47
MD	630	9	1.43	0	0.00	621	98.57
ME	505	0	0.00	0	0.00	505	100.00
MH	2	0	0.00	0	0.00	2	100.00
MI	1185	4	0.34	8	0.68	1173	98.99
MN	1043	1	0.10	0	0.00	1042	99.90
MP	3	0	0.00	0	0.00	3	100.00
MS	541	0	0.00	0	0.00	541	100.00
MT	411	0	0.00	0	0.00	411	100.00
NC	1101	12	1.09	5	0.45	1084	98.46
ND	418	0	0.00	0	0.00	418	100.00
NE	632	0	0.00	0	0.00	632	100.00
NH	292	0	0.00	0	0.00	292	100.00
NJ	747	0	0.00	0	0.00	747	100.00
NM	438	0	0.00	0	0.00	438	100.00
NV	257	0	0.00	0	0.00	257	100.00
NY	2246	4	0.18	0	0.00	2242	99.82
OH	1487	6	0.40	40	2.69	1441	96.91
OK	791	0	0.00	0	0.00	791	100.00
OR	494	6	1.21	0	0.00	488	98.79
PA	2244	8	0.36	0	0.00	2236	99.64
PR	177	0	0.00	0	0.00	177	100.00
PW	2	0	0.00	0	0.00	2	100.00
RI	91	0	0.00	0	0.00	91	100.00
SC	543	7	1.29	0	0.00	536	98.71
SD	418	0	0.00	0	0.00	418	100.00
TN	814	2	0.25	0	0.00	812	99.75
TX	2726	0	0.00	1	0.04	2725	99.96
UT	359	0	0.00	0	0.00	359	100.00
VA	1277	8	0.63	17	1.33	1252	98.04
VI	16	0	0.00	0	0.00	16	100.00
VT	309	0	0.00	0	0.00	309	100.00
WA	744	2	0.27	0	0.00	742	99.73
WI	919	3	0.33	0	0.00	916	99.67
WK	711	0	0.00	2	0.28	709	99.72
WM	342	0	0.00	0	0.00	342	100.00
WV	936	17	1.82	3	0.32	916	97.86
WY	198	0	0.00	0	0.00	198	100.00
Totals	42914	122	0.28	100	0.23	42692	99.48

We believe that 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 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 invite 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.

C. Clinical Laboratory Fee Schedule

In the CY 2014 PFS final rule with comment period (78 FR 74440–74445, 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, 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 are not proposing any revisions to payment amounts for test codes on the CLFS based on technological changes and are proposing to remove § 414.511. Instead, 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 requirements for furnishing services in RHCs and FQHCs, see Chapter 13 of the CMS Benefit Policy Manual.)

In the May 2, 2014 final rule with comment period (79 FR 25436) 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,'' 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 section 1861(aa)(2)(iii) 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. The regulations at § 405.2413(a)(6), § 405.2415(a)(6), and § 405.2452(a)(6) 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.

2. Provisions of Proposed Rule

To provide RHCs and FQHCs with as much flexibility as possible to meet their staffing needs, we are proposing 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 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.

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 XX 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 propose 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 propose 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 signals 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 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 propose 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. If finalized, this regulation will provide clear legal authority for 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 Safe Guards (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, 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 proposed rule. 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 Center 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 invite 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 are proposing a new subpart K in part 403 to implement section 1115A of the Act.

F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

1. Background

On April 1, 2014, the PAMA was enacted and section 216 addresses Medicare payment and coverage policies for clinical diagnostic laboratory testing. In regard to coverage policies, section 216 amended the statute by adding section 1834A(g) of the Act, which establishes mandates related to issuance of local coverage policies by the Medicare Administrative Contractors (MACs) for clinical diagnostic laboratory tests. The law states: ''A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1869(f)(2)(B)), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).''

Section 1869(f)(2)(B) of the Act defines a local coverage determination (LCD) as ''a determination by a fiscal intermediary or a carrier under Part A or Part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A) of the Act.''

Since the new law requires that the process for making local coverage determinations be used as the vehicle for local coverage policies for clinical diagnostic laboratory tests, it is important that we carefully consider the LCD process that is used today and determine if there are certain, limited aspects of the LCD process that may provide an opportunity to better fit the needs of this particular area of medicine. In addition to the current LCD process, we will examine how the LCD process was applied to a pilot project for molecular diagnostic tests as we are learning important lessons from this ongoing pilot. We believe lessons learned from this project can be applied to all clinical diagnostic laboratory testing and not just molecular diagnostic tests (which are encompassed under the PAMA requirement for local coverage policies). In this proposed process, we will review the current LCD process, as well as the pilot in support of a proposal to create, consistent with the requirements set forth under the PAMA, an expedited LCD process for clinical diagnostic laboratory testing.

The current LCD process (Table 18) requires that a draft LCD be published in the Medicare Coverage Database (MCD). This serves as a public announcement that an LCD is being developed. Once a draft LCD is published, at least 45 calendar days are provided for public comment. We note that the National Coverage Determination (NCD) process only requires a 30-day public comment period after a proposed NCD is published. This timeframe is based on the NCD statutory requirements under 1862(l) of the Act and in our experience at the national policy level, 30 days is generally adequate to allow for robust public comment.

After the draft LCD is made public, MACs are required to hold an open meeting to discuss the draft LCD with stakeholders. In addition to the open meeting, the MACs present the draft policy to the Carrier Advisory Committee (CAC). These two aspects of LCD development can be time-consuming and may involve logistical complications that extend the length of time it takes to reach a final policy. We note that unlike the national advisory committee, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), the CAC meetings and open stakeholder meetings are scheduled to discuss many LCD policies at a time as opposed to narrowly focusing on one policy. Due to the resources required, the constant development of LCDs and scheduling considerations, MACs do not hold ad hoc meetings. Both the open stakeholder meetings and the CAC meetings are scheduled far in advance, generally at the start of the calendar year before MACs know which policies will be presented in these forums. The timing of the open stakeholder meeting, CAC meeting, and public release of the draft LCD are all factors in determining which LCDs are on the agendas. Because of these scheduling issues, some LCDs may not have to wait as long for a CAC meeting or an open stakeholder meeting while others could have lengthy delays. In contrast, at the national level, MEDCACs are not convened for every NCD and separate open meetings are also not a part of the NCD process. Based on our experience with the NCD process over the past decade, we believe that public input is now readily available through more technologically advanced mechanisms of collecting public comment. For example, the information gathered and knowledge gained from the LCD open stakeholder meetings may now be acquired more broadly through the collection of public comments via web-based applications. CMS and its contractors are receiving more input on their policies because of these technology advances, which were not as available to the public when the LCD manual was originally written approximately 25 years ago. Medical literature, clinical practice guidelines, complicated charts and graphs can now be easily submitted electronically through the public comment process. Questions or follow-up information from a specific commenter can be addressed through conference calls or email. In addition, through these processes, all public comments are available to everyone rather than to the few people who attend meetings in

person. In addition to publishing a draft LCD, MACs publish a document that provides a summary of all of the comments received and responses to those comments. This allows the public to understand the reasoning behind the final LCD and to know that all of the public comments were taken under consideration as the MAC developed the final policy. Since this information is made readily available in writing, an open meeting is no longer necessary for the public to be heard. There are more efficient methods available to the public to submit comments and additional evidence that supports or rejects the application of a draft LCD.

Somewhat different considerations apply to CACs, which are state-specific bodies representing the clinical expertise of a geographic area. CACs allow a unique opportunity for CAC members to provide practical information regarding a draft policy since they are the entities actually delivering services in the community. However, like MEDCACs, a CAC may not be needed in all instances for the creation or revision of an LCD. CAC meeting agendas can quickly fill up with draft LCDs since the CAC meetings are scheduled far in advance. We believe CACs may be a better resource and used more efficiently in the development of LCDs if the MAC is able to select which draft LCDs are presented to a CAC for discussion, as opposed to taking all LCDs to the CAC. Of note, NCDs that go before the MEDCAC are selected by the agency and it is not part of the process for every NCD.

Under the current LCD process, after the close of the comment period and the required meetings, the MAC publishes a final LCD. As stated earlier, the MAC must also respond to any comments received, via a comment/response document. A notice period of at least 45 calendar days is then required before the LCD can take effect. While it takes time for the provider community and the claims processing systems to adapt to changes in coverage, a notice period delays the date of when coverage may be become effective.

In addition to evaluating the effectiveness of certain aspects of the LCD implementation process, we are also examining a pilot project that CMS launched with a single MAC, Palmetto GBA, on November 1, 2011. While the pilot discussed in this section only includes molecular diagnostic (genetic) laboratory tests, a subset of all clinical diagnostic lab tests, we believe the pilot's design and some of the lessons learned from the pilot can be applied to all clinical diagnostic laboratory tests

For background, the universe of molecular diagnostic laboratory tests is vast and the current LCD process can be lengthy for some of these innovative tests, which are technically complex. For example, multiple molecular diagnostic tests designated to diagnose the same disease may rely on different underlying technologies and, therefore, have significantly different performance characteristics. It would not be appropriate to assume that all tests for a particular condition behave the same. Because of these complexities, we have an obligation to consider the evidence at a granular level; that is, to ensure coverage of the appropriate test for the appropriate Medicare beneficiary.

The pilot project's long-term goal was to assist clinicians by determining whether the molecular diagnostic tests they order actually perform as expected and, thus, ultimately improve clinical care. This goal stemmed from concerns that some tests were being marketed directly to physicians without information regarding the test's performance. The pilot project sought to achieve this goal by identifying all of the molecular diagnostic tests that Medicare was covering in the Palmetto MAC jurisdiction. This required the ability to uniquely identify tests through test registration and assignment of an identifier. In addition, the MAC reviewed clinical statements made by the manufacturer for each molecular diagnostic test to ensure the test was delivering what was being claimed. Essentially, the pilot project facilitated claims processing, tracked utilization, and determined clinical validity, utility and coverage through technical assessments of published test data.

As part of the pilot project, Palmetto wrote a single molecular diagnostic laboratory testing LCD that outlined the framework they would follow in determining coverage of all molecular diagnostic tests in their jurisdiction. Additionally, that LCD included a list of covered molecular diagnostic tests. Moreover, Palmetto issued several articles addressing various other aspects of the LCD implementation process, including coding guidelines, billing and medical review procedures. There is much information that is not contained in the body of an LCD that is necessary for consistent and predictable claims processing and payment.

We believe a process that ensures transparency and stakeholder participation can be achieved without utilizing the current LCD process in its entirety. Some key aspects of the process should be maintained such as allowing public comment on draft LCDs and requiring MAC responses to public comments. However, we believe other aspects could be streamlined to allow more timely decisions and a more efficient process.

2. Proposed New LCD Process for Clinical Diagnostic Laboratory Tests

After assessment of the current LCD process, the Palmetto pilot project, the requirements of the PAMA, and the vast field of clinical diagnostic laboratory tests, including molecular diagnostic tests, we are proposing a revised LCD process for all new draft clinical diagnostic laboratory test LCDs published on or after January 1, 2015. This process would carefully balance the need for an expedited process to handle the vast number of clinical diagnostic laboratory tests, including the rapidly growing universe of molecular diagnostic tests. The National Institutes of Health (NIH)-sponsored Genetic Testing Registry (GTR) currently includes 16,000 registered genetic tests for over 4,000 conditions (*www.ncbi.nlm.nih.gov/gtr/*). We have a responsibility to ensure that appropriate tests are covered by Medicare and that coverage is limited to tests for which the test results are used by the ordering physician in the management of the beneficiary's specific medical problem (as required in § 410.32(a)). Coverage for diagnostic laboratory tests may be achieved through various policy vehicles, including an NCD, LCD, or claim-by-claim adjudication at the local contractor level. For most molecular diagnostic tests, coverage has been determined by the MACs, through LCDs or claim-by-claim adjudication. Few such tests have been the subject of an NCD, to date. This concentration of coverage decisions at the local level, and the responsibility of the agency to allow coverage of appropriate tests provide additional reasons to provide MACs with a more streamlined LCD process.

Based on these considerations, we are proposing a new LCD process that would apply only to clinical diagnostic laboratory tests. Specifically, we are proposing to establish a process MACs must follow when developing clinical diagnostic laboratory test LCDs and encouraging MACs to collaborate on such policies across jurisdictions. We propose that the process apply to all new clinical diagnostic laboratory testing draft LCDs published on or after January 1, 2015. Consistent with Chapter 13, section 13.7.3 of the Medicare Program Integrity Manual (PIM), however, we further propose that this process will not apply to clinical diagnostic laboratory testing LCDs that are being revised for the following

reasons: to liberalize an existing LCD; being issued for a compelling reason; making a non-substantive correction; providing a clarification; making a non-discretionary coverage or diagnosis coding update; making a discretionary diagnosis coding update that does not restrict; or revising to effectuate an Administrative Law Judge's decision on a Benefits Improvement and Protection Act (BIPA) 522 challenge.

The proposed new process would allow any person or entity to request an LCD or the MAC to initiate an LCD regarding clinical diagnostic laboratory testing. After this external request or internal initiation, the MAC would publish a draft LCD in the Medicare Coverage Database (*http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*), thereby making the draft LCD publicly available. Next, a minimum of 30 calendar days for public comment would be required. We note that in the event that stakeholders and/or members of the public are not able to submit comments within the 30 calendar day window, the MAC would have discretion to extend the comment period. We would expect the draft LCDs to outline the criteria the MAC would use when determining whether a specific clinical diagnostic laboratory test or a group of tests are covered or non-covered. The MAC would review, analyze, and take under consideration all public comments on the draft LCD. For draft LCDs where the MAC determines that a CAC meeting would contribute to the quality of the final policy, the MAC has discretion to take draft LCDs to the CAC. In the event the MAC involves the CAC in the development of an LCD, we would require that the public comment period be extended to allow for the CAC to be held before the final policy is issued. The MAC would be required to respond to all public comments in writing and post their responses on a public Web site. As a final step, the MAC would publish the final LCD in the Medicare Coverage Database no later than 45 calendar days after the close of the comment period. We believe 45 days to be an adequate time for the MAC to take all comments under consideration, prepare responses to those comments, and develop a final policy.

The final LCD would be effective immediately upon publication. This effective date would be different than under the current LCD process (which includes a notice period of at least 45 calendar days before a final LCD is effective); however, based on our experience with NCDs, which are also effective upon publication, we believe this is an efficient mechanism to make tests available to beneficiaries more quickly.

3. Reconsideration Process

The proposed process for developing clinical diagnostic laboratory testing LCDs would not change the LCD reconsideration process as outlined in the PIM in Chapter 13. This section of the manual allows interested parties the opportunity to request reconsideration of an LCD. Under the proposed process, the MACs would continue to implement all sections of the PIM that relate to the LCD reconsideration process.

4. LCD Challenge Process

The proposed process for clinical diagnostic laboratory testing LCDs would also not change any of the current review processes available to an aggrieved party. An aggrieved party would continue to be able to challenge an LCD according to the requirements set out in 42 CFR part 426.

As discussed previously, we believe an administratively more efficient process is needed for local coverage determinations for clinical diagnostic laboratory testing. If we continue to require that MACs follow all steps in the current LCD process, we fear that LCDs will not be able to be finalized quickly enough for even a fraction of the thousands of new clinical diagnostic (particularly molecular) tests developed each year.

We believe this proposed new process for clinical diagnostic laboratory tests will allow for public dialogue, notification of stakeholders, and expedited beneficiary access to covered tests. Table 18 summarizes the differences between the current LCD process and the proposed new LCD process for the development of clinical diagnostic laboratory testing policies.

TABLE 18—COMPARISON OF CURRENT LCD PROCESS VERSUS PROPOSED LCD PROCESS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS

Current LCD process	Proposed LCD process for clinical diagnostic laboratory tests
Issue Draft LCD in Medicare Coverage Database, which identifies criteria used for determining coverage under statutory "reasonable and necessary" standard.	Issue Draft LCD in Medicare Coverage Database, which identifies criteria used for determining coverage under statutory "reasonable and necessary" standard.
Public comment period of 45 calendar days	Public comment period of 30 calendar days with option to extend.
Present LCD at CAC & discussion at open stakeholder meetings	Optional CAC meeting. No requirement for open stakeholder meeting.
Publication of Comment/Response Document and final LCD (no specified time of publication after the close of the comment period).	Publication of Comment/Response Document and final LCD within 45 calendar days of the close of the draft LCD comment period.
Notice period of 45 calendar days with the final LCD effective the 46th calendar day.	Final LCD effective on the date of publication.
Interested parties may request reconsideration of an LCD	Interested parties may request reconsideration of an LCD.
An aggrieved party may further challenge an LCD	An aggrieved party may further challenge an LCD.

In summary, we believe this proposed process would meet all the requirements of the PAMA, would be open and transparent, would allow for public input, and would be administratively efficient. We are proposing this process only for clinical diagnostic laboratory testing when coverage policies are developed by a MAC through an LCD; it would not apply to the NCD process or other vehicles of coverage including claim-by-claim adjudication. We believe the proposed process would balance stakeholders' concerns about ensuring an open and transparent process with the ability to efficiently review clinical laboratory tests for coverage. We encourage public comment on all aspects of this proposed process.

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 focus 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 propose 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 propose 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 propose that the cross reference to § 405.803 in § 405.450(a) be replaced with a cross reference to § 498.3(b). We also propose that the cross reference to § 405.803 in § 405.450(b) be replaced with a cross reference to § 405.924. We also propose 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 propose 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.''

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 [contractor] 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 providing services in place of the departed physician in the departed physician's former medical group, while the departed physician is also providing 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 contractor 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 contractor 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 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 are seeking 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. Solicitation 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 are soliciting comments on the policy for substitute physician billing arrangements. We note that any regulations would be proposed in a future rulemaking with opportunity for public comment. Through this solicitation, we hope to understand better current industry practices with respect to 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. Therefore,

we are soliciting comments on the following:

(1) How physicians and other entities are currently utilizing the services of substitute physicians and billing for such services. We are interested in specific examples, including the circumstances that give rise to the need for the substitute physician, the types of services furnished by the substitute physician, the billing for the services of the substitute physician, the length of time that the substitute physician's services are needed or used, and any other information relevant to the substitute physician billing arrangement.

(2) When a physician is ''unavailable'' to provide services for purposes of section 1842(b)(6)(D) of the Act. We are particularly interested in comments from physicians, medical groups and other entities that utilize the services of substitute physicians regarding when a regular physician is ''unavailable.''

(3) Whether we should limit substitute physician billing arrangements to those ''between the two physicians'' (rather than between a medical group, employer or other entity and the substitute physician) as stated in section 1842(b)(6)(D)(ii) of the Act.

(4) Whether we should permit the sequential use of multiple substitute physicians provided that each substitute physician furnishes services for the unavailable physician for no more than 60 continuous days.

(5) Whether we should have identical or different criteria for substitute physician billing arrangements under sections 1842(b)(6)(D)(ii)(I) and (II) of the Act; that is, whether we should treat reciprocal substitute physician billing arrangements differently than paid (or locum tenens) substitute physician billing arrangements.

(6) Whether substitute physicians furnishing services to Medicare beneficiaries should be required to enroll in the Medicare program.

(7) Whether entities submitting claims for services furnished by substitute physicians should include on the CMS–1500 claim form or on the appropriate electronic claim the identity of the substitute physician and, if so, whether the CMS–1500 claim form or the appropriate electronic claim should be revised to accommodate such a requirement.

(8) Whether we should place limitations on the use of the substitute physician and billing for his or her services (for example, limits on the length of time that an individual substitute physician may provide services to replace a particular departed physician; limits on the overall length of time that substitute physicians may provide services to replace a particular departed physician; a requirement that the departing physician be a party to the substitute physician billing arrangement; or permitting the use of a substitute physician only where a demonstrated staffing need can be shown). We are also seeking comments regarding whether these limitations should be different depending on the circumstances underlying or requiring the use of the substitute physician.

(9) Whether we should limit or prohibit the use of substitute physician billing arrangements in certain programs or for certain purposes (for example, the Medicare Shared Savings Program or determining whether a physician is a member of a group practice for purposes of the physician self-referral law).

(10) The impact of substitute physician billing arrangements on CMS programs that rely on the Provider Enrollment, Chain and Ownership System (PECOS) (for example, the Medicare Shared Savings Program), enforcement of the physician self-referral law, and program integrity oversight.

(11) Additional program integrity safeguards that should be included in our substitute physician billing policy to protect against program and patient abuse. These could include, but are not limited to, qualifications for substitute physicians related to exclusion status, quality of care, or licensure and certifications.

(12) Any other issues that we should consider in determining whether to propose regulations interpreting section 1842(b)(6)(D) of the Act.

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 to the Act, as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The 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 (Sunshine Act)'' 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 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 are proposing a change to § 403.904(g) to correct an unintended consequence of the current regulatory text. Additionally, at § 403.904(c)(8), we are proposing 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 propose 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 propose 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 propose 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, 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 seek comments on both alternatives presented, including commenters' suggestions about what standards, if any, CMS should incorporate.

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 making 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 propose to revise § 403.904(c)(8) to require applicable manufacturers to report the marketed name for all covered and non-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.

Section 403.904(d)(3) requires the reporting of stock, stock option or any other ownership interest. We are proposing 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 seek 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.

4. Summary of Proposed Changes

As noted above in this section, we propose the following changes to Part 403, subpart I:

- Deleting the definition of ''covered device'' at § 403.902.
- Deleting § 403.904(g) and redesignating the remaining paragraphs in that section.
- Revising § 403.904(c)(8) to require the reporting of the marketed name of the related covered and non-covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological or medical supply.
- Revising § 403.904(d) to require the reporting of the reporting of stock, stock option or any other options as distinct categories.

Data collection requirements would begin January 1, 2015 according to this proposed rule for applicable manufacturers and applicable group purchasing organizations.

J. Physician Compare Web site

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act, required that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals (EPs) who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

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 required 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 Web site 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 when selecting quality measures for Physician Compare. We also continue to get input from stakeholders through a variety of means including rulemaking and different forms of stakeholder outreach (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 Web site, 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 Web site functionality and usability. 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.

Currently, Web site users can view information about approved Medicare professionals such as name, primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare Assignment status, education, 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 Web site the names of individual EPs who satisfactorily report under the 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 propose 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 Web site in 2016).

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 participating in the Group Practice Reporting Option (GPRO) under the 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 propose 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 Web site in 2016).

As we finalized in the 2014 PFS final rule with comment period (78 FR 74450), we will publicly report the names of those EPs who report the 2014 PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative on Physician Compare in 2015 by including a check mark in the quality programs section of the profile page. We propose 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). 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 Web site in 2015 (78 FR 74450).

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.[5] 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 late 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, CMS 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 (''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 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, CMS can investigate the extent to which each quality measure is correlated with related, previously validated, measures. CMS 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

[5] 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.

measure are computed using contemporaneous data. In this context, the previously validated measure should measure a health outcome related to the outcome of interest.

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 Web site 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 Web site (*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 69166–69167), 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 are 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.[7]

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 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) are 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 through 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 19 for a summary of our final policies for public reporting data on Physician Compare.

TABLE 19—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 and PQRS GPRO, successful e-prescribers under eRx, and participants in EHR for groups and individuals as applicable.
2012	2014	WI	5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices with a minimum sample size of 25 patients and Shared Savings Program ACOs.

TABLE 19—SUMMARY OF PREVIOUSLY FINALIZED POLICIES FOR PUBLIC REPORTING ON PHYSICIAN COMPARE—Continued

Data collection year	Public reporting year	Reporting mechanism(s)	Quality measures and data for public reporting
2013	2014	WI, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and PQRS GPRO, successful e-prescribers under eRx, and participants in EHR, as well as for EPs who earn a Maintenance of Certification (MOC) 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 WI for groups of 25 or more EPs with a minimum sample size of 20 patients. Will include composites for DM and CAD, if feasible.
2013	Expected to be December 2014	WI	5 CG–CAHPS summary measures for groups of 100 or more EPs reporting via the WI and 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 PQRS GPRO, participants in EHR, as well as for EPs who earn a Maintenance of Certification (MOC) Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2014	Expected to be late 2015	WI, EHR, Registry	All measures reported via the GPRO WI, 13 EHR, and 16 Registry GPRO measures are also available for group practices of 2 or more EPs and Shared Savings Program ACOs with a minimum sample size of 20 patients. 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 that are collected through a Registry, EHR, or claims with a minimum sample size of 20 patients.
2014	Expected to be late 2015	Registry, EHR, or Claims	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. Proposals for Public Data Disclosure on Physician Compare in 2015 and 2016

We are continuing the expansion of public reporting on Physician Compare by proposing to make an even broader set of quality measures available for publication on the Web site. We started the phased approach with a small number of possible PQRS GPRO web interface measures for 2012, and have been steadily building on this to provide Medicare consumers with more information to help them make informed health care decisions. As a result, we are now proposing to increase the measures available for public reporting.

We previously finalized in the CY 2014 PFS final rule with comment period (78 FR 74450) to make available for public reporting all PQRS GPRO measures collected in 2014 via the web interface. We now propose 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.[6] Similarly, all measures reported by Shared Savings Program ACOs would be

[6] Tables Q1–Q27 detail proposed changes to available PQRS measures. Additional information on PQRS measures can be found on the CMS.gov PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.*

available for public reporting on Physician Compare. As with all quality measures proposed for inclusion on Physician Compare, only measures that prove to be valid, reliable, and accurate upon analysis and review at the conclusion of data collection will be included on the Web site. Also, we propose that measures must meet the public reporting criteria of a minimum sample size of 20 patients. We propose to include an indicator of which reporting mechanism was used and only measures deemed statistically comparable would be included on the site.[7] We propose to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file. However, we propose that not all of these measures necessarily would be included on the Physician Compare profile pages. Consumer testing has shown including too much information and/or measures that are not well understood by consumers on these pages can negatively impact a consumer's ability to make informed decisions. Our analysis of the measure data once collected, consumer testing, and stakeholder feedback would determine specifically which measures are published on profile pages on the Web site. Statistical analyses will ensure the measures included are statistically valid and reliable and comparable across data collection mechanisms. And, 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. As 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.

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.

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.

In addition to making all 2015 PQRS GPRO measures available for public reporting, we seek comment 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 will 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

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. We have received ample feedback from stakeholders indicating such scores are strongly desired. Composite scores, generally, have also proven to be critical for providing consumers a better way to understand quality measure data as composites provide a more concise, easy to understand picture of physician quality. Therefore, we plan to analyze the data once collected to establish the best possible composite, which would help consumers use these quality data to make informed health care decisions.

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 propose 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 propose to follow this methodology using the 2014 PQRS GPRO data, however.

As outlined for the Shared Savings Program, we propose 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 points systems 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

[7] 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.

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.

Understanding the value consumers place on patient experience data and the commitment to reporting these data on Physician Compare, we propose publicly reporting in CY 2016 patient experience data from 2015 for all group practices of 2 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 propose to publicly report for 2015 data on Physician Compare in 2016 the 12 summary survey measures previously finalized for 2014 data:

- 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 propose 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 propose 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 Web site.

We previously finalized in the 2014 PFS final rule with comment period (78 FR 74454) that 20 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 propose to expand on this in two ways. First, we propose to publicly report these same 20 measures for 2013 PQRS data in early 2015. Publicly reporting these 2013 individual measures will help ensure individual level measures are made available as soon as possible. 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.

Second, we propose 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.[8] This will provide the opportunity for more EPs to have measures included on Physician Compare, and it will provide more information to consumers to make informed decisions about their health care. As with group-level measures, we propose 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 measure data once collected, consumer testing, and stakeholder feedback would determine specifically which measures are published on profile pages on the Web site. In this way, quality information at the individual practitioner level would be available, as has been regularly requested by Medicare consumers, but consumers will not be overwhelmed with too much information on each EPs profile page.

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 seek comment to create composites and publish composite scores by grouping measures based on the PQRS measure groups, if technically feasible. We will 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. In addition, we propose to use the same methodology outlined above for group practices to develop benchmarks for individual practitioners. As noted for group practices, we believe that providing composite scores and benchmarks will give consumers the tools needed to most accurately interpret the quality data published on Physician Compare.

Previously, we indicated an interest in including specialty society measures on Physician Compare. We now seek comment on posting these measures on the Web site. We also seek comment on the option of linking from Physician Compare to specialty society Web sites 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 are working to identify possible societies to reach out to, and seek comment on the concept, as well as potential specific society measures of interest.

Finally, we propose 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

[8] Tables Q1–Q27 detail proposed changes to available PQRS measures. Additional information on PQRS measures can be found on the CMS.gov PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.*

measures and non-PQRS measures.[9] 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 therefore providing more quality data to consumers to help them make informed decisions. The QCDR would be required to declare during their self-nomination if they plan to post data on their own Web site and allow Physician Compare to link to it or if they will provide data to us for public reporting on Physician Compare. We propose 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 propose 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 measure data once collected, consumer testing, and stakeholder feedback would determine specifically which measures are published on profile pages on the Web site.

Table 20 summarizes the Physician Compare proposals detailed in this section. We solicit comments on all proposals. Increasing the measures available for public reporting on Physician Compare at both the individual and group level will help accomplish the Web site's twofold purpose:

- Provide more information for consumers to encourage informed patient choice.
- Create explicit incentives for physicians to maximize performance.

TABLE 20—SUMMARY OF PROPOSED DATA FOR PUBLIC REPORTING

Data collection year	Publication year	Data type	Reporting mechanism	Proposed quality measures and data for public reporting
2013	2015	PQRS	Registry, EHR, or Claims	Twenty 2013 PQRS individual measures collected through a Registry, EHR, or claims mirroring the measures finalized for 2014 (78 FR 74454).
2015	2016	Multiple	Web Interface, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS and PQRS GPRO, participants in EHR, and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2015	2016	PQRS GPRO & ACO GPRO.	Web Interface, EHR, & Registry.	All 2015 PQRS GPRO measures reported via the Web Interface, EHR, and Registry 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 2015 QCDR data available for public report on Physician Compare at the individual level or aggregated to a higher level of the QCDR's choosing.

K. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

This section contains the proposed requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments (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 proposed requirements will primarily focus on our proposals related to 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, in developing these proposals, we focused on aligning our requirements with other quality reporting programs, such as the Medicare EHR Incentive Program for Eligible Professionals, the Physician Value-Based Payment Modifier (VM), and the Medicare Shared Savings Program, where and to the extent appropriate and feasible. In previous years, we have made various strides in our ongoing efforts to align the reporting requirements in CMS' various quality reporting programs to reduce burden on the eligible professionals and group practices that participate in these programs. Particularly through the QCDR option, we are exploring opportunities to align with quality reporting programs that exist outside of CMS where and to the extent appropriate and feasible. We continued to focus on alignment as we developed our proposals for the 2017 PQRS payment adjustment below.

The PQRS regulation is located at 42 CFR 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

[9] *http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2014_PQRS_IndClaimsRegistry_MeasureSpecs_SupportingDocs_12132013.zip.*

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 (CAHs) were previously not able to participate in the PQRS. Due to a change we made in the manner in which eligible professionals in CAHs are reimbursed by Medicare, it is now feasible for eligible professionals in CAHs to participate in the PQRS. Although eligible professionals in CAHs 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 CAHs 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 propose to make this revision throughout § 414.90.

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 CG–CAHPS 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. Please note that we are not proposing to make changes to the claims-based reporting mechanism.

a. Proposed 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 are proposing that—in addition to proposing to require 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 propose to define that term in section III.K.2.a., and wishes to meet the proposed 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 21. In accordance with this proposal, we are proposing 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 21 for which the registry's participating eligible professionals are able to report. We are proposing to require that qualified registries be able to report on all cross-cutting measures specified in Table 21 for which the registry's participating eligible professionals are able to report, rather than proposing to require a minimum of 2, so that eligible professionals and group practices using qualified registries to report PQRS measures would have the flexibility in choosing which cross-cutting measures to report, and to report on as many cross-cutting measures specified in Table 21 as they are able.

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. While, 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 propose 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).

In addition, we seek comment on whether to propose in future rulemaking to allow more frequent submissions of data, such as quarterly or year-round submissions, rather than having only one opportunity to submit quality measures data as is our current process.

We invite public comment on these proposals.

b. Proposed 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 Web site 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 propose to continue applying these requirements to direct EHR products and EHR data submission vendor products for 2015 and beyond. For 2015 and beyond, we also propose 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.

Additionally, we seek comment on whether to propose in future rulemaking to allow more frequent submissions of data, such as quarterly or year-round submissions, rather than having only one opportunity to submit quality measures data as is our current process.

We invite public comment on these proposals.

c. Proposed Changes to the Requirements for the QCDR

In the CY 2014 PFS final rule with comment period, we established certain requirements for entities to become QCDRs for the purpose of having their participating eligible professionals meet the criteria for satisfactory participation in a QCDR for purposes of the PQRS incentives and payment adjustments (78 FR 74465 through 74474).

Specifically, in accordance with the final criterion that required eligible professionals to report on at least 1 outcome measure, we required that an entity possess at least 1 outcome measure for which its participating eligible professionals may report (78 FR 74470). As we explain in further detail in section III.K. of this proposed rule, we are proposing that an eligible professional wishing to meet the proposed criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment report on at least 3 outcome measures (or if less than 3 outcome measures are available for reporting, 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). Accordingly, we are proposing to amend the requirement for the 2017 PQRS payment adjustment 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).

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). Although we believe such a limit is still necessary because the QCDR option is still new and we are still gaining familiarity with the measures available for reporting under the QCDRs, we believe it is appropriate to increase the number of non-PQRS that may be reported by QCDRs. We have received comments from entities currently undergoing the QCDR qualification process who wish to submit data on additional measures and we believe that accepting additional quality measures data is important, as it provides a better and more complete picture of the quality of care provided by eligible professionals. Therefore, we are proposing to change this limit from 20 measures to 30. In other words, 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 proposed 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.

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 propose 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.

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 are proposing 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.

In the CY 2014 PFS proposed rule, we proposed that, to be considered a QCDR, an entity would be required to demonstrate that it has a plan to publicly report its quality data through a mechanism where the public and registry participants can view data about individual eligible professionals, as well as view regional and national benchmarks (78 FR 43363). Due to stakeholder feedback against this proposal, as well as comments requesting more details surrounding this proposal, we did not finalize this proposed requirement in the CY 2014 PFS final rule with comment period. However, we noted that we would revisit this proposal in future years (78 FR 74471). Because of our ongoing interest in providing transparency to the public for quality measures data that is reported under the PQRS, we again propose the requirement that an entity make available to the public the quality measures data for which its eligible professionals report. To clarify this proposal, we propose 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.

With respect to when the quality measures data must be publicly reported, we propose 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 proposed 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. We also propose 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.

Please note that, in making this proposal, 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 proposed requirement, it would be sufficient for a QCDR to publicly report performance rates of eligible professionals through means such as, but not excluding, board or specialty Web sites, performance or feedback reports, 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 we 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.

Based on CMS 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 provide 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 propose 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). We are adding this proposal because we received questions from entities wishing to become QCDRs who are engaged in quality improvement activities but use an external organization for purposes of quality measures data collection, calculation, and transmission. We believe that it may be appropriate to classify the entity as a QCDR so long as the entity meets the definition of a QCDR by the date for which we require that a QCDR must be in existence (that is, January 1 the year prior to the year for which the entity seeks to become a QCDR (78 FR 74467)). 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.

• In addition, we propose 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.

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 propose 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 occurring in 2015).

Additionally, we seek comment on whether to propose in future rulemaking to allow more frequent submissions of data, such as quarterly or year-round submissions, rather than having only one opportunity to submit quality measures data as is our current process.

We seek public comment on these proposed changes to the requirements for the QCDR.

d. Proposed 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 propose 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). 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.

Furthermore, we seek comment on whether to allow more frequent submissions of data, such as quarterly or year-round submissions, rather than having only one opportunity to submit quality measures data as is our current process.

We seek public comment on these proposals.

2. Proposed 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. Proposed 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, we are proposing to modify § 414.90(j) and propose 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 propose 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 21. 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 note that, unlike the criterion we finalized for the 2014 PQRS incentive, we are proposing to require an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter, as we propose to define that term below, 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. 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 note 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 proposing to require reporting of at least 2 cross-cutting measures specified in Table 21, we propose 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 proposals

require reporting of at least 2 cross-cutting measures specified in Table 21.

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 proposed cross-cutting measures specified in Table 21. The MAV process we are proposing to implement for claims and registry 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*.

We seek public comment on our proposed satisfactory reporting criterion for individual eligible professionals reporting via claims or registry for the 2017 PQRS payment adjustment.

b. Proposed 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 that is CEHRT or an EHR data submission vendor 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 are proposing to modify § 414.90(j) and propose the following criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR that is CEHRT or an EHR data submission vendor 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 seek public comment on this proposal.

c. Proposed 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 are proposing 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 are proposing 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, however, in this section III.K of this proposed rule, we are proposing to change the definition of a PQRS measures group.

We seek public comment on our proposed satisfactory reporting criterion for individual eligible professionals reporting measures groups via registry for the 2017 PQRS payment adjustment.

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. Proposed 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, *and* 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 propose 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 are proposing 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 are proposing 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 understand 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 are allowing 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 seek public comment on these proposals.

4. Proposed 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 proposed 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.*

In the CY 2014 PFS final rule with comment period, we established a deadline of September 30 of the applicable reporting period (that is, September 30, 2014, for reporting periods occurring in 2014) for a group practice to register to participate in the GPRO (78 FR 74456). While 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. Since participation in the VM is tied to PQRS participation as discussed in section III.N. of this proposed rule, we have found that having a GPRO registration deadline so late in time would not allow us to collect information related to group practice participation in time to provide PQRS and VM participants with feedback reports earlier in time. Therefore, in an effort to provide timelier feedback, we are proposing 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. We invite public comment on this proposal.

a. Proposed 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 propose 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 propose 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 proposed 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 are proposing to reduce the patient sample size 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 are proposing 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 recognize 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 proposed 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 this proposed rule, we are proposing 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 propose to adopt the attribution methodology changes proposed for the VM into the GPRO web interface beneficiary assignment methodology.

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 (i.e., 0 percent) responses for a particular module or measure. Since we are moving solely towards the implementation of PQRS payment adjustments, we seek 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 21). 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.

We invite public comment on these proposals.

b. Proposed 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 propose here to modify § 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 21. 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. In addition, if a group practice does not report on at least 1 cross-cutting measure and the group practice has at least 1 eligible professional who sees at least 1 Medicare patient in a face-to-face encounter, the MAV will also allow us to determine whether a group practice should have reported on any of the proposed cross-cutting measures specified in Table 21. The MAV process we are proposing 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 EHR Incentive Program and in accordance with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, for those group practices that choose to report using an EHR, we propose to 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 invite public comment on these proposals.

c. Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via 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 are proposing the following 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:

Proposed Option 1: If a group practice 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 would report all CAHPS for PQRS survey measures via a certified 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 all applicable measures. Of these 6 measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would be required to report on at least 1 measure in the cross-cutting measure set specified in Table 21. We note that this proposed option to report 6 additional measures, including at least 1 cross-cutting measure if a group practice sees at least 1 Medicare patient in a face-to-face encounter, is consistent with the proposed criterion for satisfactory reporting for the 2017 PQRS payment adjustment via qualified registry. However, unlike the proposed criterion for satisfactory reporting for the 2017 PQRS payment adjustment via qualified registry without CG–CAHPS, we are only proposing the requirement to report 1 measure in the cross-cutting measure set specified in Table 21 instead of 2 measures as the CAHPS for PQRS measures are contained in the cross-cutting measure set.

Consistent with the proposed 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. 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 a measure application validity process (MAV), which would allow us to determine whether a group practice should have reported quality data codes for additional measures and/or measures covering additional NQS domains.

In addition, if a group practice does not report on at least 1 cross-cutting measure and the group practice has at least 1 eligible professional who sees at least 1 Medicare patient in a face-to-face encounter, the MAV will also allow us to determine whether a group practice should have reported on any of the proposed cross-cutting measures specified in Table 21. The MAV process we are proposing 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.*

Proposed Option 2: If a group practice 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 would report all CAHPS for PQRS survey measures via a certified 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 that is CEHRT. If less than 6 measures

apply to the group practice, the group practice must report all applicable 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. We note that this proposed option to report 6 additional measures is consistent with the proposed criterion for satisfactory reporting for the 2017 PQRS payment adjustment via EHR without CAHPS for PQRS, since the CAHPS for PQRS survey only addresses 1 NQS domain.

Proposed Option 3: Alternatively, if a group practice chooses to use the GPRO web interface in conjunction with reporting the CAHPS for PQRS survey measures, we propose the following criterion for satisfactory reporting for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified 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.

Furthermore, as was required for reporting periods occurring in 2014 (78 FR 74485), we propose 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. We note 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 CMS 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 are proposing to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals, we propose that CAHPS for PQRS would be optional for groups of 25–99 and 2–24 eligible professionals. We note that all group practices that would be required to report or voluntarily elect to report CAHPS for PQRS would need to select and pay for a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf.

We invite public comment on these proposals.

d. Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Selected To Participate in the GPRO To Report the CAHPS for PQRS Survey Measures via a CMS-Certified Survey Vendor for the 2018 PQRS Payment Adjustment and Subsequent Years

We believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes and, moving forward, we would like to emphasize the importance of collecting patient experience of care data through the use of CAHPS for PQRS. Therefore, based on our authority under section 1848(m)(3)(C) of the Act to determine the criteria for satisfactory reporting for group practices under section 1848(m)(3)(C) of the Act, we are proposing to require that, in conjunction with other satisfactory reporting criteria we establish in future years, beginning with the 12-month reporting period for the 2018 PQRS payment adjustment, and for subsequent years, group practices comprised of 25 or more eligible professionals that are participating in the GPRO report and pay for the collection of the CAHPS for PQRS survey measures. We understand that the cost of administering the CAHPS for PQRS survey may be significant, so we are proposing this requirement well in advance of the year in which it would be first effective in order to provide group practices with early notice so that their practices may adjust accordingly.

We invite public comment on these proposals.

e. 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 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. 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. 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. We seek comments on how to allow for reporting of the S–CAHPS survey measures for the 2018 PQRS payment adjustment and beyond.

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 rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that include the NQS domain for care coordination and communication.
- Measures that include the NQS domain for patient experience and patient-reported outcomes.
- Measures that address efficiency, cost and resource use.

a. Proposed PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section contains our proposals for the inclusion or removal of measures in PQRS for 2015 and beyond. We are classifying all proposed measures against six domains based on the NQS's six priorities, as follows:

(1) *Patient Safety.* These are measures that reflect the safe delivery of clinical services in all healthcare settings. These measures may address a structure or process that is designed to reduce risk in the delivery of healthcare or measure the occurrence of an untoward outcome such as adverse events and complications of procedures or other interventions.

(2) *Person and Caregiver-Centered Experience and Outcomes.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level. These are measures of organizational structures or processes that foster both the inclusion of persons and family members as active members of the health care team and collaborative partnerships with providers and provider organizations or can be measures of patient-reported experiences and outcomes that reflect greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(3) *Communication and Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication. They may also be measures that reflect outcomes of successful coordination of care.

(4) *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines or measures of patient-centered outcomes of disease states.

(5) *Community/Population Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. They may be

measures of processes focused on primary prevention of disease or general screening for early detection of disease unrelated to a current or prior condition.

(6) *Efficiency and Cost Reduction.* These are measures that reflect efforts to lower costs and to significantly improve outcomes and reduce errors. These are measures of cost, resource use and appropriate use of healthcare resources or inefficiencies in healthcare delivery.

Please note that the PQRS quality measure specifications for any given proposed PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the proposed PQRS quality measures that were selected for reporting in 2014 and beyond, please note that detailed measure specifications, including the measure's title, for the proposed 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, we note that the measure titles for measures available for reporting via EHR may change. To the extent that the EHR Incentive Program 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. 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 note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.*

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 24, we are proposing 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 note 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 propose to keep the measure available for reporting under the PQRS and therefore not finalize our proposal to remove the measure. In addition, if, after the display of this proposed rule, we discover additional measures within the current PQRS measure set that a measure owner/developer can no longer maintain, we propose to remove these measures from reporting for the PQRS beginning in 2015. We will discuss any such instances in the CY 2015 PFS final rule with comment period.

In addition, we note that we have received feedback from stakeholders, particularly first-time participants who find it difficult to understand which measures are applicable to their particular practice. In an effort to aide 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 Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.* Please note that these groups of measures are meant to provide guidance to those 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 propose that, if we discover 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.

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. Proposed Cross-Cutting Measure Set for 2015 and Beyond

In accordance with our proposed 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 are proposing the following 18 cross-cutting measure set specified in Table 21 for 2015 and beyond. Please note that our rationale for proposing each of these measures is found below the measure description. We have also indicated the PQRS reporting mechanism or mechanisms through which each proposed measure could be submitted. In addition to seeking comment on this proposed cross-cutting measure set specified in Table 21, we seek comment on other measures that commenters believe should be included in this proposed cross-cutting measure set for 2015 and beyond.

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TABLE 21: Proposed 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
N/A /N/A	N/A	Community /Population Health	**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 who received help quitting if identified as a tobacco user. **Rationale:** CMS is proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This is a preventive measure targeting support of adolescent populations in quitting smoking, which represents a clinical gap in the program.Several provider types are able to report this measure in a variety of outpatient settings including Pediatricians, Family Practice physicians, and Internists. This measure is also applicable for a broad patient sample further positioning this measure as cross-cutting.	NCQA / NCIQM			X			X	
0028 /226	138 v2	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. **Rationale:** This measure has been identified as a cross-cutting measure as it represents a screening assessment for tobacco use that most eligible professionals may perform and is applicable to most adult patients. This measure is applicable in various outpatient settings and can be reported by most eligible professionals that see adult patients. This measure was finalized for reporting in the PQRS in the CY 2014 PFS final rule (see Table 52 at 78 FR 74498).	AMA-PCPI	X		X	X	X	X	ACO MU2 Million Hearts
0038 /240	117 v2	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. **Rationale:** This measure is clincally significant for all pediatric patients and is applicable to a	NCQA				X			MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[Y]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			variety of eligible professionals that provide services to pediatric patients making it reportable by a large segment of eligible professionals.This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).								
0418 /134	2v3	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. **Rationale:** This measure represents a screening assessment for depression that most eligible professionals may perform and is applicable to most adult patients, making it broadly reportable as a cross-cutting measure. This measure is also applicable in a variety of outpatient settings, enhancing the reportability of this measure. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	CMS/QIP	X		X	X	X	X	ACO MU2
0419 /130	68v 3	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. **Rationale:** This measure targets the documentation of current medications in the medical record, which is a clinical process that most eligible professionals may perform and is applicable to most adult patients. This measure is also applicable in various outpatient settings. For these reasons, this measure is identified as cross-cutting.This measure was finalized for reporting in the PQRS in the CY 2014 PFS final rule (see Table 52 at 78 FR 74498).	CMS/QIP	X		X	X	X	X	ACO MU2
0421 /128	69v 2	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18-64 years BMI ≥ 18.5 and < 25 **Rationale:** This measure has been identified as	CMS/QIP	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
			a cross-cutting measure as it represents a screening assessment for BMI that most eligible professionals may perform and is applicable to most adult patients in various outpatient settings. This measure was finalized for reporting in the PQRS in the CY 2014 PFS final rule (see Table 52 at 78 FR 74498).								
N/A /374	50v 2	Communica tion and Care Coordinatio n	**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. **Rationale:** This measure represents communication between a variety of eligible professionals and promotes positive outcomes for patients. It is reportable by a broad spectrum of providers. In addition,this measure is applicable to most adult patients, further enhancing its reportability across disciplines and speciaties.. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	CMS/BAH				X			MU2
0097 /046	N/A	Communica tion and Care Coordinatio n	**Medication Reconciliation:** Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. 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. **Rationale:** This measure has been identified as a cross-cutting measure as it represents the clinical process of medication reconciliation, which most eligible professionals may perform and is applicable to most elderly patients in various inpatient/outpatient settings, making this a broadly reportable measure. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	AMA-PCPI / NCQA			X				
0041 /110	147 v2	Community /Population 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. **Rationale:** This measure represents a screening assessmentfor influenza immunization that most eligible professionals may perform and is applicable to most adult and pediatric patients. This measure is applicable in various outpatient settings.This measure was finalized for reporting in the PQRS in the CY 2014 PFS final rule (see Table 52 at 78 FR 4498).	AMA-PCPI	X		X	X	X	X	ACO MU2
0043 /111	127 v2	Community /Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a	NCQA	X		X	X	X	X	ACO MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[y]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			pneumococcal vaccine. **Rationale:** This measure represents a screening assessment for pneumonia vaccination that most eligible professionals may perform and is applicable to most elderly patients. This measure is also applicable in various outpatient settings, which further enhances its reportability across various disciplines and specialties. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).								
N/A /317	22v 2	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. **Rationale:** This measure represents a common screening assessment for high blood pressure that most eligible professionals perform and is applicable to most adult and elderly patients in a variety of inpatient/outpatient settings. As such, this measure has been identified as cross-cutting.This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	CMS/QIP	X		X	X	X	X	ACO MU2 Million Hearts
0101 /318	139 v2	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. **Rationale:** This measure represents a fall risk screening assessment that most eligible professionals may perform and is applicable to most elderly patients. This screen tool may be commonly used by providers serving this patient population in a variety of outpatient settings and as such this measure has been identified as a cross-cutting measure. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	NCQA				X	X		ACO MU2
0326 /047	N/A	Person and Caregiver-Centered Experience and Outcomes	**Care Plan:** Percentage of patients aged 65 years and older who have an care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an care plan. **Rationale:** This measure has been identified as a cross-cutting measure as it represents the development of a care plan that most eligible professionals may perform and is applicable to most elderly patients in various inpatient/outpatient settings. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	AMA-PCPI / NCQA	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
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. **Rationale:** This measure represents a screening assessment for pain and follow-up care that most eligible professionals may perform and is applicable to most adult patients seen in a variety of outpatient settings. For these reasons, this measure has been identified as a cross-cutting measure. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	CMS/QIP	X		X			X	
AQA Adopted /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. **Rationale:** This measure has been identified as a cross-cutting measure as it represents a functional assessment that physical therapist/chriopratic eligible professionals may perform and is applicable to most adult patients. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	CMS/QIP	X		X				
0005 &0006 /321	N/A	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 **Rationale:** This measure has been identified as an outcome-based cross-cutting measure due to it directly measureing patient satisfaction of office visits. The data collected by the survey provides information based on a group practice's performance of the patient's care. This information potentially impacts a variety of eligible professionals based on the survay data received from patients. This measure was finalized for reporting in the PQRS in the CY 2013 PFS final rule (see Table 95 at 77 FR 69215).	AHRQ		X					ACO

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 v2	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. **Rationale:** This measure has been identified as a cross-cutting measure as it represents patient care that is clinically appropriate for many eligible professionals treating adult patients. This measure is applicable to most adult patients in various outpatient settings. This measure was finalized for reporting in the PQRS in the CY 2014 PFS final rule (see Table 52 at 78 FR 4498).	NCQA	X		X	X	X	X	ACO MU2 Million Hearts
N/A/ N/A	N/A	Community /Population Health	**Screening for Hepatitis C Virus (HCV) for Patients at High Risk:** Percentage of patients with one or more of the following: a history of injection drug use, patients who received blood transfusions prior to 1992, OR patients who were born in the years 1945–1965 who received a one-time hepatitis C virus (HCV) antibody test. **Rationale:** CMS is proposing this measure based on our exception authority under I 848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section I 890(a) of the Act (that is, the NQF). This measure is complementary of Hepatitis C measures currently in the program, representing a clinical gap not currently captured by PQRS. This measure is also proposed as a cross-cutting measure because screening for Hep C is applicable for a broad patient sample and a variety of eligible professionals in various outpatient settings.	AGA / AASLD / 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.

c. Proposed New PQRS Measures Available for Reporting for 2015 and Beyond

Table 22 contains the additional measures we are proposing to include in the PQRS measure set for CY 2015 and beyond. Please note that not all of the proposed cross-cutting measures may appear in Table 22, as some of the propose cross-cutting measures specified in Table 21 were finalized in the CY 2013 or CY 2014 PFS final rules with comment period. Please note that our rationale for proposing each of these measures is found below the measure description. We have also indicated the PQRS reporting mechanism or mechanisms through which each proposed measure could be submitted.

TABLE 22: Proposed 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
1879 /N/A	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). **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure represents a PQRS program gap of measures targeting a patient population with active psycosis or psychiatric disorders. This measure is also reportable by behavioral/mental health providers.	CMS / FMQAI			X				
N/A /N/A	N/A	Patient Safety	**Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder:** The measure calculates the percentage of individuals 18 years of age or greater as of the beginning ofthe measurement period 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). **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a PQRS program gap of measures targeting a patient population with active psychosis or psychiatric disorders. This measure is also reportable by behavioral/mental health providers.	CMS/FMQ AI	X						
N/A /N/A	N/A	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Reoperation Rate:** % of surgeries for primary rhegmatogenous retinal detachment where the retina remains attached after only one surgery. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This is an outcome measure that represents a new clinical concept for PQRS. This measure will be reportable by Opthamologists.	AA			X				
N/A /N/A	N/A	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery Success Rate:** Percentage (%) of Retinal Detachment cases achieving flat	American Association of Eye and			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
			retinas 6 months post surgery. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This is an outcome measure that represents a new clinical concept for PQRS. This measure will be reportable by Opthamologists.	Ear Centers of Excellence / The Australian Council on Healthcare Standards							
N/A /N/ A	N/A	Person and Caregiver-Centered Experience and Outcomes	**ALS Patient Care Preferences:** Percentage of patients diagnosed with ALS who were offered at least once annually assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice). **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This is a process measure that represents a new clinical concept for PQRS, filling a current clinical gap in the program for neurodegenerative disease. This measure would be reportable for eligible professionals within the scope of neurology.	AAN			X				
N/A /N/ A	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 a hepatitis C virus (HCV) antibody test or HCV ribonucleic acid (RNA) test within the 12 month reporting period. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure addresses a clinical gap in PQRS by targeting active injection drug users. This measure is reportable by Gastroenterologists, Hepatologists, Infectious Disease providers and Primary Care providers.	AGA / AASLD / PCPI			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 1 year (9 to 15 months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of	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
			the Act (that is, the NQF). This outcome measure represents a clinical gap in the program and is reportable by Neurosurgery and Orthopedic Surgery providers.								
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 atraumatic low back pain. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a program gap and targets a provider group currently under represented in the program, imaging specialists and radiologists.	ACEP			X				
N/A /N/ A	N/A	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule requiring unplanned vitrectomy):** Rupture of the posterior capsule during anterior segment surgery requiring vitrectomy. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This outcome measure is reportable by Opthamologists and is proposed to be included within the Cataracts Measure Group, complementing the existing cataracts measures with a clinical focus not currently caprtured within PQRS.	AAEECE / ACHS			X			X	
N/A /N/ A	N/A	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients who achieve planned refraction within +-1,0 D. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This outcome measure is reportable by Opthamologists and is proposed to be included within the Cataracts Measure Group, complementing the existing catarcts measures with a clinical focus not currently caprtured within PQRS.	AAEECE / ACHS			X			X	
188 5 /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 score > 9 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	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
			diagnosed and existing depression identified during the defined measurement period whose current PHQ-9 score indicates a need for treatment. **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is an outcome measure that complements existing depression measures within the program.								
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 have an inadequate response to antiviral treatment for whom antiviral treatment was discontinued. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This process measure represents a clinical complement to existing Hepatitis C measures currently included in the program.	AGA / AASLD / PCPI			X				
N/A /N/ A	N/A	Person and Caregiver-Centered Experience and Outcomes	**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 clinician 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/clinician and the patient that includes all of the following: • Treatment choices appropriate to genotype • Risks and benefits • Evidence of effectiveness • Patient preferences toward the outcome of the treatment. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This patient experience measure represents a clinical complement to existing Hepatitis C measures currently included in the program. This measure is proposed to be included within the Hepatitis C Measure Group.	AGA / AASLD / PCPI			X			X	
N/A /N/ A	N/A	Communicati on and Care Coordination	**Follow-up After Hospitalization for Mental Illness:** 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:	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
			- 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. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a clinical gap in the program. This measure would complement the existing mental health clinical concepts within PQRS.								
N/A /N/ A	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. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a gap in care for patients who receive device therapy for heart arrythmia. This outcome measure expands upon measures that are available for electrophysiologist to report within PQRS. At this time, PQRS has one other measure, PQRS #348: HRS-3: Implantable Cardioverter Defibrillator (ICD) Complications Rate, reportable within the scope of electrophysiology.	HRS			X				
N/A /N/ A	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. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a gap in care for patients who receive device therapy for heart arrythmia. This outcome measure expands upon measures that are available for electrophysiologist to report within PQRS. At this time, PQRS has one other measure, PQRS #348: HRS-3: Implantable Cardioverter Defibrillator (ICD) Complications Rate, reportable within the scope of electrophysiology.	HRS			X				
140 7 /N/	N/A	Community/P opulation Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their	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
A			13th birthday. **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is a process measure that complements existing childhood immunication measures already in the program. This measure would be reportable by Pediatricians, Family Practice physicians, and Internists.								
N/A /N/ A	N/A	Communicati on and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of non small cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a program gap in measures for the pathology specialty.	CAP	X		X				
N/A /N/ A	N/A	Communicati on 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. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a program gap in measures for the pathology specialty.	CAP	X		X				
662 /N/ A	N/A	Communicati on and Care Coordination	**Median Time to Pain Management for Long Bone Fracture:** Median time from emergency department arrival to time of initial oral or parenteral pain medication administration for emergency department patients with a principal diagnosis of long bone fracture (LBF). **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This outcome measure provides alignment across programs and settings and addresses a clinical gap in the program.	CMS/OFM Q			X				
N/A /N/ A	N/A	Communicati on 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. **Rationale:** We are proposing this measure based on our exception authority under section 1848(k)(2)(C)(ii) of the Act that provides an	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
			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). This measure represents a program gap in measures for the pathology specialty.								
N/A /N/ A	N/A	Person and Caregiver-Centered Experience and Outcomes	**Optimal Asthma Care- Control Component:** 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. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This patient centered outcome measure will replace PQRS #064 (Asthma: Assessment of Asthma Control-Ambulatory Care Setting) as it represents a more robust clinical outcome for asthma care.	MNCM			X				
N/A /N/ A	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. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a clinical gap in the program for patients with percutaneous coronary intervention (PCI). This is a new clinical concept proposed for reporting within PQRS.	ACC-AHA			X				
N/A /N/ A	N/A	Effective Clinical Care	**Recurrence or amputation following endovascular infrainquinal lower extremity revascularization:** Percentage of patients undergoing endovascular infrainguinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) require repeat ipsilateral revascularization or any amputation within 1 year. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would complement the existing vascular health clinical concepts within PQRS.	SVS			X				
N/A /N/ A	N/A	Effective Clinical Care	**Recurrence or amputation following open infrainquinal lower extremity revascularization:** Percentage of patients undergoing open infrainguinal revascularization for non-limb threatening ischemia (claudication	SVS			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
			or asymptomatic) who require ipsilateral repeat revascularization or any amputation within 1 year. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure would complement the existing vascular health clinical concepts within PQRS.								
N/A /N/ A	N/A	Community/P opulation Health	**Screening for Hepatitis C Virus (HCV) for Patients at High Risk:** Percentage of patients with one or more of the following: a history of injection drug use, patients who received blood transfusions prior to 1992, OR patients who were born in the years 1945–1965 who received a one-time hepatitis C virus (HCV) antibody test. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure is complementary of Hepatitis C measures currently in the program, representing a clinical gap not currently captured.	AGA / AASLD / AMA-PCPI			X				
N/A /N/ A	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 were screened with either ultrasound, triple-contrast CT or triple-contrast MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period. **Rationale:** We are proposing this measure 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 that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). This process, screening measure represents a clinical complement to existing Hepatitis C measures currently included in the program. This measure is proposed to be included within the Hepatitis C Measure Group.	AGA / AASLD / AMA-PCPI			X			X	
N/A /N/ A	N/A	Community/P opulation Health	**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. **Rationale:** We are proposing this measure 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 that have been endorsed by the	NCQA / NCIQM			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
			entity with a contract under section 1890(a) of the Act (that is, the NQF). This measure represents a clinical gap in the program, targeting support of adolescent populations in quitting smoking. This preventive measure supports pediatric patients and is reportable by Pediatricians, Family Practice physicians, and Internists. This is also a cross cutting measure.								

¥ 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 23, we specify the measures for which we are proposing a NQS domain change for reporting under the PQRS. Please note the rationale we have for each measure for which we are proposing a NQS domain change below.

TABLE 23: Proposed 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
0097/046	N/A	Patient Safety	Communication and Care Coordination	**Medication Reconciliation:** Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. 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 **Rationale:** CMS is recategorizing this measure from the patient safety domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure ensures that the key information needed to make clinical decisions is deliberatley organized in a conscious effort and available to patients and providers.			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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services.			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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure ensures that the key information needed to make clinical decisions is deliberatley organized in a conscious effort and is available to patients and their caregivers.						X	
N/A/2	N/A	Effective Clinical	Communication and	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or						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
93		Care	Care Coordination	caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure ensures that the key information needed to make clinical decisions is deliberatley organized in a conscious effort and is available to patients and their caregivers.							
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 (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure ensures that the key information needed to make clinical decisions is deliberatley organized in a conscious effort and is available to patients and their caregivers.						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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure ensures that the key information needed to make clinical decisions is deliberately organized in a conscious effort and is available to patients and providers as well as communicated between health care providers.			X				
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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the communication and care coordination domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure						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
				constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.							
N/A/303	N/A	Effective Clinical Care	Person and Caregiver-Centered Experience and Outcomes	**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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the person and caregiver-centered experience and outcomes domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure encompases the inclusion of patient or family-reported experiences (outcomes) as members of the health care team in a collaborative partnerships with providers.			X			X	
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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the efficiency and cost reduction domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects the efficient use of health care services in the provision of patient care.			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:** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, without clavulante, as a first line antibiotic at the time of diagnosis **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the efficiency and cost reduction domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects the efficient use of health care services in the provision of patient care.			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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines			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 categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.							
N/A/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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.			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 or colectomy surgery **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.						X	
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 **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.						X	
0043/111	127 v2	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. **Rationale:** CMS is recategorizing this measure from the effective clinical care domain to the community/ population health domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure is a measurement of process focused on the prevention of and screening for disease.	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			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
				Rationale: CMS is recategorizing this measure from the communication and care coordination domain to the effective clinical care domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects care that is consistent with systematically acquired evidence to determine whether an intervention, diagnostic test, or therapy produces better outcomes than alternatives.							
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 **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the effective clinical care domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects care that is consistent with systematically acquired evidence to determine whether an intervention, diagnostic test, or therapy produces better outcomes than alternatives.						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 **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the effective clinical care domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects care that is consistent with systematically acquired evidence to determine whether an intervention, diagnostic test, or therapy produces better outcomes than alternatives.						X	
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 **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the efficiency and cost reduction domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects the efficient use of health care services in the provision of patient care.	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)			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
				Rationale: CMS is recategorizing this measure from the communication and care coordination domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.							
N/A/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) **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurrence of a health outcome that results from the absence of appropriate structures or processed.			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 **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.			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 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 **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the patient safety domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects care that is consistent with systematically acquired evidence to determine whether an intervention, diagnostic test, or therapy produces better outcomes than alternatives.			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
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 **Rationale:** CMS is recategorizing this measure from the communication and care coordination domain to the person and caregiver experience and outcomes domain in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure encompases the inclusion of patient or family-reported experiences (outcomes) as members of the health care team in a collaborative partnerships with providers.		X					ACO

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 24, we specify the measures we are proposing to remove from reporting under the PQRS. Please note that the rationale we have for each measure we are proposing to remove is specified after the measure title and description.

TABLE 24: Measures Proposed for Removal 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
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI /NCQA	X		X				
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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI /NCQA	X		X				
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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that does not add clinical value to PQRS. LVF testing is a basic assessment for patients with heart failure. Furthermore, the MAP strongly recommends removal of this measure as these types of process measures do not meaningfully contribute to improved outcomes based on a body of literature that demonstrates that lack of association.	CMS/QIP			X				
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	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
		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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.								
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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI /NCQA	X		X				
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 record **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AAN	X		X				
N/A295	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. **Rationale**: CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	ABIM						X	
N/A297	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. **Rationale**: CMS recommends removal due tothe measure steward indicating they will no longer maintain this measure. In addition, this is a process measure that is distal to the outcome and has not been shown to improve patient outcomes.. Furthermore, MAP strongly recommends removal as these types of process measures do not meaningfully contribute to improved outcomes.	ABIM						X	
N/A298	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.	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
		Rationale: CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.								
N/A299	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. **Rationale**: CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	ABIM						X	
N/A300	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). **Rationale**: CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	ABIM						X	
N/A302	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. **Rationale**: CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	ABIM						X	
0087/0014	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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X				
0270/0020	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) **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X			X	
0268/0021	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients	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
		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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.								
0271/0022	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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X			X	
0239/0023	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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X			X	
0092/0028	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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that has been substantially adopted for initial treatment of patients suffering from acute myocardial infarction when clinically indicated.	AMA-PCPI NCQA	X		X				
0269/0030	Patient Safety	**Perioperative Care:Timing of Prophylactic Antiobiotic—Administering Physician:** Percentage of surgical patients aged 18 years and older who receive an anesthetic when undergoing procedures with the indications for prophylactic	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
		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) **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.								
0240/0031	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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that is currently included within inpatient standards of care to improve patient outcomes for those diagnosed with ischemic or intracranial stroke when clincially indicated.	AMA-PCPI NCQA	X		X				
0325/0032	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 **Rationale:** CMS recommends removal 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.	AMA-PCPI NCQA	X		X				
0241/0033	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge **Rationale:** CMS recommends removal 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.	AMA-PCPI NCQA			X				
0243/0035	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	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
		Rationale: CMS recommends removal due to this measure representing a clinical concept that is currently included within hospital standard of care to decrease risk of choking for patients diagnosed with ischemic or intracranial stroke when clinically indicated.								
0244/0036	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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that is currently included within inpatient standard of care to improve quality of life for patients diagnosed with ischemic or intracranial stroke when clinically indicated.	AMA-PCPI NCQA	X		X				
0637/0045	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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X				
0099/0049	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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X				
0001/0064	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) **Rationale:** CMS recommends removal due to this measure representing a 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.	AMA-PCPI NCQA			X			X	
0393/0083	Effective	**Hepatitis C: Confirmation of Hepatitis C**	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
	Clinical Care	**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 **Rationale:** CMS recommends removal due to eligible professionals are consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.								
0103/0106	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 (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 **Rationale:** CMS recommends removal due to this measure representing a clinically diagnostic reference that is commonly utilized in order to determine mental health disorders, therefore it does not add clinical value to PQRS.	AMA-PCPI	X		X				
1666/0123	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 **Rationale:** CMS recommends removal due to this measure representing a medical concept of completion of a required diagnostic level in order to provide erythropoiesis-stimulating agent when clinically appropriate.	AMA-PCPI	X		X			X	
0566/0140	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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		X				
0051/0142	Effective Clinical Care	**Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-**	AMA-PCPI	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
		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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that does not add clinical value to PQRS due to assessment of patients' current medications is crucial to patient safety. Furthermore, the measure steward has indicated they will no longer maintain this measure.								
0508/0146	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" **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA	X		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 **Rationale:** CMS recommends removal as this measure is duplicated within PQRS with current measure HIV Medica Visit Frequency (PQRS #340)s.	HRSA			X			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) **Rationale:** CMS recommends removal as evidence-based guidelines have changed regarding lipid control.	ABIM						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 **Rationale:** CMS recommends removal as this measure is duplicated within PQRS with current measure Preventive Care and Screening: Influenza Immunization (PQRS #110).	AGA						X	
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 **Rationale:** CMS recommends removal as this measure is duplicated within PQRS with current	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
		measure Pneumonia Vaccination Status for Older Adults (PQRS #111).								
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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that does not add clinical value to PQRS because in order to provide effective treatment for IBD, documentation of type, anatomic location and activity would be essential for effective treatment of IBD.	AGA						X	
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AAN	X		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 **Rationale:** CMS recommends removal due to the clinical concept of medical referral being a common practice in order to provide effective treatment for patients.	AQC	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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that is initiated within the inpatient setting and does not add clinical value to PQRS as an outpatient based measure.	ACCF AHA			X				
AQA Adopted/247	Effective Clinical Care	**Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence:**	AMA-PCPI NCQA	X		X				AQA

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.								
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 **Rationale:** CMS recommends removal as this measure is duplicated within the Physician Quality Reporting System as a subset of an existing measure Preventive Care and Screening for Clinical Depression for Follow-up Plan (PQRS #134)).	AMA-PCPI NCQA	X		X				AQA
N/A/231	Effective Clinical Care	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients aged 5 through 64years 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 **Rationale:** CMS recommends removal as this measure is duplicated within PQRS with current measure Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (PQRS 226).	AMA-PCPI NCQA	X		X			X	
N/A/232	Effective Clinical Care	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting**: Percentage of patients aged 5 through64 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 **Rationale:** CMS recommends removal as this measure is duplicated within PQRS with current measure Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (PQRS 226).	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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in	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
		care.								
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 older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy) **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	STS			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 **Rationale:** CMS recommends removal as evidence-based guidelines have changed regarding lipid control. This measure is also being proposed for removal from the GPRO WI.	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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that does not add clinical value to PQRS. LVF testing is basic assessment for patients with heart failure.	AMA-PCPI ACCF AHA			X			X	
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	STS			X			X	
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting	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 on this measure with performance rates close to 100% suggesting there is no gap in care.								
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	STS			X			X	
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	STS			X			X	
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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	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 **Rationale:** CMS recommends removal due to eligible professionals consistently meeting performance on this measure with performance rates close to 100% suggesting there is no gap in care.	AMA-PCPI NCQA			X			X	
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 **Rationale:** CMS recommends removal due to this measure representing a clinical concept that is currently accepted standard treatment for patients that receive lower extremity revascularization when clinically indicated.	SVS			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	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
		months **Rationale:** CMS recommends removal due to measure steward indicating they will no longer maintain this measure.								
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 **Rationale:** CMS recommends removal due to this measure representing clinical assessments commonly utilized to provide effective treatment for patients diagnosed with back pain.	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 **Rationale:** CMS recommends removal due to this measure representing clinical assessments commonly utilized to provide effective treatment for patients diagnosed with back pain.	NCQA						X	
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 **Rationale:** CMS recommends removal due to this measure representing clinical recommendations that are commonly provided for patients diagnosed with back pain when clinically indicated.	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 **Rationale:** CMS recommends removal due to this measure representing clinical recommendations that are commonly provided for patients diagnosed with back pain when clinically indicated.	NCQA						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 **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI			X			X	
0102/052	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy:** Percentage of patients aged 18 years and older	AMA-PCPI			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
		with a diagnosis of COPD and who have an FEV_1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.								
0050/109	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI			X				
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 **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI/NCQA						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 **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI/NCQA						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 **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI/NCQA						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 **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI/NCQA						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	AMA-PCPI	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 (e.g., x-ray, MRI, CT, etc.) that were performed. **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.								
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. **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI			X			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 < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	AMA-PCPI			X				
N/A/336	Communication and Care Coordination	**Maternity Care: Post-Partum Follow-Up and Care Coordination:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning **Rationale:** CMS recommends removal due to the measure steward indicating they will no longer maintain this measure.	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 25 below, we specify our proposals to change the way in which previously established measures in the PQRS will be reported beginning in 2015. Please note that, in Table 25, we provide our explanation as to how we are proposing to change the way the measure is reported, as well as a corresponding rationale for this proposed change.

TABLE 25: 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
006 7/6		Effective Clinical Care	**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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ACCF AHA			X		X	X	ACO
008 6/12	143 v2	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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X	X			MU2
008 9/19	142 v2	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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X	X			MU2
004 5/24		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to	AMA-PCPI 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
			move the PQRS program away from claims reporting.								
004 6/39		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X			X	
004 8/40		Effective Clinical Care	**Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X				
013 4/43		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	STS			X			X	
009 7/46		Communication and Care Coordination	**Medication Reconciliation:** Percentage of patients aged 65 years and older **discharged from any inpatient facility** (e.g., 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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to	AMA-PCPI 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
			move the PQRS program away from claims reporting.								
010 0/50		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X				
009 0/54		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X				
037 7/67		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ASH			X				
037 8/68		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	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
038 0/69		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ASH			X				
037 9/70		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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ASH			X				
038 7/71	140 v1	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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ASCO NCCN			X	X		X	MU2
038 5/72	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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ASCO NCCN			X	X		X	MU2
038	129	Efficiency	**Prostate Cancer: Avoidance of Overuse of Bone**	AMA-			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
9 /102	v3	and Cost Reduction	**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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	PCPI							
039 0 /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 risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist) **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI			X				
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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	NCQA			X	X	X	X	MU2
003 4 /113	130 v2	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	NCQA			X	X	X	X	MU2
005 5 /117	131 v2	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 in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period	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
			Rationale: CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.								
006 2 /119	134 v2	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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	NCQA			X	X		X	MU2
166 8 /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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI			X			X	
AQ A Ado pted /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]) and proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI			X			X	AQA
056 3 /141		Communicati on 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	AMA-PCPI 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
			Rationale: CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.								
005 6 /163	123 v2	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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	NCQA			X	X	X	X	ACO MU2
065 9 /185		Communicati on and Care Coordination	**Endoscopy /Polyp Surveillance: 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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI ASCO			X				
038 6 /194		Effective Clinical Care	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI NCQA			X				
065 1 /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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims	ACEP			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.								
065 2 /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) **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	ACEP			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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AAN			X				
065 8 /320		Communicati on and Care Coordination	**Endoscopy/Polyp Surveillance: 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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI			X				
152 5 /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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to	AMA-PCPI ACCF AHA			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
			move the PQRS program away from claims reporting.								
N/A /327		Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI			X				
166 7 /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 **Rationale:** CMS proposes to remove the claims reporting option for this measure as CMS seeks to move the PQRS program away from claims reporting.	AMA-PCPI			X				
010 4/10 7	161 v2	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 **Rationale:** CMS initially wanted to propose removal of this measure as it is a process measure that is low bar. However, to maintain alignment with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.	AMA-PCPI				X			MU2
010 5/9	128 v2	Effective Clinical Care	**Anti-Depressant Medication Management:** "Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12	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
			weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months). **Rationale:** CMS initially wanted to propose removal of this measure as it is a process measure that is analytically challenging to report. However, to maintain alignment with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.								
006 4/2	163 v2	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 **Rationale:** CMS initially wanted to propose removal of this measure as it would be duplicative of the new diabetes composite. However, to maintain alignment with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.	NCQA				X			MU2 Million Hearts
008 8/00 18	167 v2	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 **Rationale:** 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, to maintain alignment with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.	AMA-PCPI NCQA				X			MU2
006 8/20 4	164 v2	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	NCQA				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
			(AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period **Rationale:** CMS initially wanted to propose removal of this measure due to changing clinical guidelines (ATP-4). However, to maintain alignment with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.								
007 5/24 1	182 v3	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) **Rationale:** CMS initially wanted to propose removal of this measure due to changing clinical guidelines (ATP-4). However, to maintain alignment with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.	NCQA				X			MU2 Million Hearts
002 2/23 8	156 v2	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. **Rationale:** CMS proposes to add registry as a reporting option for this measure to enhance reporting by more providers.	NCQA			X	X			MU2
039		Effective	**Hepatitis C: Ribonucleic Acid (RNA) Testing**	AMA-						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
5 /84		Clinical Care	**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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Hepatitis C measures group allows CMS to evaluate patients diagnosed with Hepatitis C to be assessed in a more comprehensive manner.	PCPI							
039 6 /85		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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Hepatitis C measures group allows CMS to evaluate patients diagnosed with Hepatitis C to be assessed in a more comprehensive manner.	AMA-PCPI						X	
039 8/87		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 whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4-12 weeks after the initiation of antiviral treatment **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure	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
			contained within the Hepatitis C measures group allows CMS to evaluate patients diagnosed with Hepatitis C to be assessed in a more comprehensive manner.								
005 4 /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 DMARD **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Rheumatoid Arthritis measures group allows CMS to evaluate patients diagnosed with Rheumatoid Arthritis to be assessed in a more comprehensive manner.	NCQA						X	
040 5 /160	52v 2	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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the HIV/AIDS measures group allows CMS to evaluate patients diagnosed with HIV/AIDS to be assessed in a more comprehensive manner.	NCQA						X	MU2
AQ A Ado pted /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) **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure	AMA-PCPI						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
			contained within the Rheumatoid Arthritis measures group allows CMS to evaluate patients diagnosed with Rheumatoid Arthritis to be assessed in a more comprehensive manner.								
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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Rheumatoid Arthritis measures group allows CMS to evaluate patients diagnosed with Rheumatoid Arthritis to be assessed in a more comprehensive manner.	AMA-PCPI						X	AQA
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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Rheumatoid Arthritis measures group allows CMS to evaluate patients diagnosed with Rheumatoid Arthritis to be assessed in a more comprehensive manner.	AMA-PCPI						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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current	AMA-PCPI						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
			requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Rheumatoid Arthritis measures group allows CMS to evaluate patients diagnosed with Rheumatoid Arthritis to be assessed in a more comprehensive manner.								
039 9 /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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Hepatitis C measures group allows CMS to evaluate patients diagnosed with Hepatitis C to be assessed in a more comprehensive manner.	AMA-PCPI						X	
040 9 /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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the HIV/AIDS measures group allows CMS to evaluate patients diagnosed with HIV/AIDS to be assessed in a more comprehensive manner.	AMA-PCPI						X	
208 2 /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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure	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
			contained within the HIV/AIDS measures group allows CMS to evaluate patients diagnosed with HIV/AIDS to be assessed in a more comprehensive manner.								
208 3 /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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the HIV/AIDS measures group allows CMS to evaluate patients diagnosed with HIV/AIDS to be assessed in a more comprehensive manner.	HRSA						X	
207 9 /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 **Rationale**: CMS proposes to make this individual measure reportable via measures group only to help mitigate the burden of eligible professionals reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the HIV/AIDS measures group allows CMS to evaluate patients diagnosed with HIV/AIDS to be assessed in a more comprehensive manner.	HRSA						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.

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We seek comment on these proposals.

d. PQRS Measures Groups

Section 414.90(b) defines a measures group as a subset of four or more Physician Quality Reporting System 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 to appropriately add measures to measures groups that only contain four measures within the measures group (78 FR 74730). We have worked with the measure owners and developers and are again proposing 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.

Specifically, we are proposing to modify section 414.90(b) to define a measures group as a subset of six or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common.

In addition, we are proposing two new measures groups that will be available for reporting in the PQRS beginning in 2015:

- *The sinusitis measures group:* We are proposing a new sinusitis measures group because this measures group represents a clinical gap within the measure group reporting option. The measures in the sinusitis measures group reflect a variety of measure types, and make up a clinically coherent and meaningful set of measures.
- *The Acute Otits Externa (AOE) measures group:* We are proposing the addition of the AOE measures group, as it focuses on the quality of care of patients with AOE by combining existing disease-specific measures with relevant cross-cutting (generic) measures.

Furthermore, we are proposing to remove the following measures groups for reporting beginning in 2015 for the following reasons:

- *Perioperative care measures group:* We are proposing to remove the perioperative care measures group from reporting in the PQRS beginning in 2015 because this measures group does not add value to the PQRS and eligible professionals are consistently meeting performance on this measure with performance rates close to 100 percent.
- *Back pain measures group:* We are proposing to remove the back pain measures group because the measure steward is not preparing these measures for re-endorsement by the National Quality Forum. We are also proposing to remove the measures group because it reflects 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.
- *Cardiovascular prevention measures group:* We are proposing 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.
- *Ischemic Vascular Disease (IVD) measures group:* We are proposing to remove the IVD 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.
- *Sleep Apnea measures group:* We are proposing to remove the Sleep Apnea measures group from reporting in the PQRS beginning in 2015 because, for a number of measures included in this group, the measure steward has indicated they will no longer maintain those measures. Those measures and their associated measure groups are proposed for removal from the program. As a result, the measures group would have less than the 6 measures proposed to be required in a measures group. Please note that this proposal is contingent on the measure steward not being able to maintain ownership of certain measures. Should we learn that a measure owner/developer is able to maintain certain measures, or that another entity is able to maintain certain measures, such that the measure group maintains a sufficient number of measures for reporting under the PQRS for the CY 2017 PQRS payment adjustment, we propose to keep the measure group available for reporting under the PQRS and therefore not finalize our proposal to remove the measure group.
- *Chronic obstructive pulmonary disease (COPD) measures group:* We are proposing to remove the COPD measures group from reporting in the PQRS beginning in 2015 because, for a number of measures included in this group, the measure steward has indicated they will no longer maintain those measures. Those measures and their associated measure groups are proposed for removal from the program. As a result, the measures group would have less than the 6 measures proposed to be required in a measures group. Please note that this proposal is contingent on the measure steward not being able to maintain ownership of certain measures. Should we learn that a measure owner/developer is able to maintain certain measures, or that another entity is able to maintain certain measures, such that the measure group maintains a sufficient number of measures for reporting under the PQRS for the CY 2017 PQRS payment adjustment, we propose to keep the measure group available for reporting under the PQRS and therefore not finalize our proposal to remove the measure group.

Tables 26 through 48 specify our proposed measures groups in light of our proposal to increase the minimum number of measures in a measures group in previously established measures groups, so that each measures group contains at least 6 measures. We invite public comment on these proposals.

TABLE 26—PROPOSED 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

TABLE 26—PROPOSED ASTHMA MEASURES GROUP FOR 2015 AND BEYOND—Continued

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
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/N/A	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: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18–64 years BMI ≥ 18.5 and < 25.	CMS/QIP

TABLE 27—PROPOSED 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 (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated.	CMS/QIP

TABLE 28—PROPOSED 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

TABLE 28—PROPOSED CATARACTS MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/ PQRS	Measure title and description	Measure developer
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/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
N/A/N/A	Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule requiring unplanned vitrectomy): Rupture of the posterior capsule during anterior segment surgery requiring vitrectomy.	AAEECE/ACHS
N/A/N/A	Cataract Surgery: Difference Between Planned and Final Refraction: Percentage of patients who achieve planned refraction within $+-1,0$ D.	AAEECE/ACHS

TABLE 29—PROPOSED 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 care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an 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 < 130/80 mmHg OR ≥ 130/80 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 30—PROPOSED CHRONIC OBSTRUCTIVE PULMONARY DISORDER (COPD) MEASURES GROUP FOR 2015 AND BEYOND

[Please note that we are proposing to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in these measures group. If a measure steward is able to maintain ownership of these measures, we plan to keep this measures group in the PQRS measure set. This Table Q10 indicates the measures that we propose will be available in this measures group should we keep this measures group in the PQRS measure set.]

NQF/ PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an 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 31—PROPOSED 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 (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	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

TABLE 32—PROPOSED 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 LVEF < 40% who were prescribed beta-blocker therapy.	AMA–PCPI

TABLE 32—PROPOSED CORONARY ARTERY DISEASE (CAD) MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/ PQRS	Measure title and description	Measure developer
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18–64 years BMI ≥ 18.5 and < 25.	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 33—PROPOSED 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 care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an 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 34—PROPOSED 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

TABLE 34—PROPOSED DIABETES MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/ PQRS	Measure title and description	Measure developer
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 35—PROPOSED 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 36—PROPOSED 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 care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an 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 37—PROPOSED 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/N/A	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 were screened with either ultrasound, triple-contrast CT or triple-contrast MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.	AGA/AASLD/AMA–PCPI
N/A/N/A	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 clinician 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/clinician and the patient that includes all of the following: • Treatment choices appropriate to genotype • Risks and benefits • Evidence of effectiveness • Patient preferences toward the outcome of the treatment	AGA/AASLD/AMA–PCPI

TABLE 38—PROPOSED 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 care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an 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 39—PROPOSED INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP FOR 2015 AND BEYOND

NQF/ PQRS	Measure title and description	Measure developer
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 for 60 or greater consecutive days 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 a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year.	AGA
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/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 40—PROPOSED 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 41—PROPOSED 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

TABLE 41—PROPOSED OPTIMIZING PATIENT EXPOSURE TO IONIZING RADIATION MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/ PQRS	Measure title and description	Measure developer
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 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 (eg, 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 42—PROPOSED 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 care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an 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 (e.g., medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually.	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 (e.g., 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 (e.g., 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 (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually.	AAN

TABLE 43—PROPOSED 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

TABLE 43—PROPOSED PREVENTIVE CARE MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/ PQRS	Measure title and description	Measure developer
0098/48	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: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter. *Normal Parameters:* Age 65 years and older BMI ≥ 23 and < 30; Age 18–64 years BMI ≥ 18.5 and < 25	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
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 44—PROPOSED 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 DMARD.	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
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
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 45—PROPOSED 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

TABLE 45—PROPOSED SINUSITIS MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
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, 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 46—PROPOSED SLEEP APNEA MEASURES GROUP FOR 2015 AND BEYOND

[Please note that we are proposing to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in these measures group. If a measure steward is able to maintain ownership of these measures, we plan to keep this measures group in the PQRS measure set. This Table Q26 indicates the measures that we propose will be available in this measures group should we keep this measures group in the PQRS measure set]

NQF/PQRS	Measure title and description	Measure developer
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter. *Normal Parameters:* Age 65 years and older BMI ≥ 23 and < 30; Age 18–64 years BMI ≥ 18.5 and < 25	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 47—PROPOSED 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 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 including history of Deep Vein Thrombosis, Pulmonary Embolism, Myocardial Infarction, Arrhythmia and Stroke.	AAHKS

TABLE 47—PROPOSED TOTAL KNEE REPLACEMENT (TKR) MEASURES GROUP FOR 2015 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
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. Proposals for 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 are proposing to remove and add measures in the GPRO Web interface measure set as reflected in Tables 47 and 48 for 2015 and beyond. Specifically, Table 47 specifies the measures we are proposing to remove for reporting from the GPRO Web interface, and Table 48 specifies the measures we are proposing to add for reporting in the GPRO Web interface. CMS is proposing to adopt Depression Remission at Twelve Months (NQF #0710) in the 2015 GPRO Web Interface reporting option for ACOs and group practices. 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 is soliciting comments regarding this proposal, including operational concerns and the technical feasibility for implementation in the 2015 GPRO Web Interface. We note that, in addition to addressing changes in evidence-based practices, we are modifying the GPRO Web interface in an effort to align with the proposed measure changes in the Medicare Shared Savings Program specified in section III.M.

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TABLE 48: Proposed Measures for Removal 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
0097/ 46	Care Coordination/ Patient Safety	Patient Safety	**Medication Reconciliation:** Percentage of patients aged 65 years and older **discharged from any inpatient facility** (e.g., 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 **Rationale:** This measure is designed to determine that medication reconciliation was done immediately following a hospital discharge whereas the medical community has indicated to us that it is better clinical practice to perform medication reconciliation at every office visit. Therefore, we propose replacing this measure with NQF #0419 Documentation of Medications in the Medical Record is designed to measure. In addition, this new replacement measure aligns with the measure used in other PQRS reporting options and MU. It is also proposed for the Medicare Shared Savings Program and proposed for a domain change to communication and care coordination to be consistent with the domain used by NQF for this measure.	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 **Rationale:** We propose 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 (**https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf ***). The new guidelines recommend treating individuals with moderate to high dose statin therapy based on cardiac risk rather than only treating high cholesterol to specific targets.	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 **Rationale:** We propose retiring 4 components of the 5 part diabetes composite measure as noted above. Specifically, we believe: ● The blood pressure component 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. ● We propose to retire 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***). The new guidelines recommend treating individuals with moderate to high dose statin therapy based on cardiac risk rather than only treating high cholesterol to specific targets ● The Tobacco Non-Use component of the Diabetes Mellitus composite is being proposed for removal from the 2015 GPRO Web Interface as this component is somewhat duplicative of the Tobacco Screening and Cessation Counseling measure (NQF 0028) and NQF 0028 is more broadly applicable. ● The Hemoglobin A1c Control (<8%) component is being proposed for removal as there are concerns that the A1c level monitored in this measure is considered too low to comprehensively evaluate the A1c is in control for the elder, frail population.	MNCM	
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) **Rationale:** We propose 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.	NCQA	MU2 Million Hearts
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 **Rationale:** CMS proposes removing this measure and replacing it with Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF #0067), added to the existing CAD composite measure in GPRO Web Interface.	NCQA	MU2 Million Hearts

TABLE 49: Proposed New Measures That Will Be Available for Reporting by 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
0059/ 1	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. **Rationale:** This is an existing measure that is being proposed as part of the new Diabetes Management composite as a more appropriate A1c component.	NCQA	MU2
0067/ 6	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 seen within a 12 month period who were prescribed aspirin or clopidogrel. **Rationale**: This is a new measure that is proposed as part of a new Coronary Artery Disease (CAD) composite due to updated clinical guidelines that affected CAD-2 (NQF 0074) Coronary Artery Disease (CAD): Lipid Control.	AMA-PCPI/ ACCF/ AHA	MU2
0070/ 7	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 **Rationale:** This is a new measure that is being proposed to create a new Coronary Artery Disease (CAD) composite due to updated clinical guidelines that affected CAD-2 (NQF 0074) Coronary Artery Disease (CAD): Lipid Control.	AMA-PCPI/ ACCF/ AHA	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 in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period **Rationale:** This is a new measure that is being proposed to create a new Diabetes Management composite due to some components of the current MNCM composite being impacted by the updated ATP4 and JNC8 clinical guidelines. We believe eye exams are an important part of quality care for diabetic patients.	NCQA	MU2
0419/ 130	Care Coordinatio n/ 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 **Rationale:** This is a new measure being proposed to replace CARE-1 (PQRS #46) Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility as this measure was not appropriate for the GPRO Web Interface per feedback from the measure steward (NCQA). Also, we received feedback from the measures community that Medication Reconciliation should be performed at all office visits and not just those visits occurring after an inpatient discharge.	CMS/QIP	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Programs
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 **Rationale**: This is a new measure being proposed as part of the Diabetes Management composite due to some components of the current MNCM composite being affected by the updated ATP4 and JNC8 clinical guidelines. We believe foot exams are an important part of quality care for diabetic patients.	NCQA	MU2
N/A/2 42	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 seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period **Rationale:** This is a new measure that is being proposed to create a new Coronary Artery Disease (CAD) composite due to updated clinical guidelines that affected CAD-2 (NQF 0074) Coronary Artery Disease (CAD): Lipid Control.	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: ● For patients with a diagnosis of ischemic vascular disease, daily aspirin use unless contraindicated **Rationale:** CMS proposes to maintain this component of the Optimal Diabetes Care composite and adding it to the new CMS Diabetes Management composite, as it represents an important quality measure for patients with multiple chronic conditions, such as diabetes and IVD.	MNCM	
0710/ 370		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. **Rationale:** This is a new measure being proposed as it reflects a clinical concept not currently addressed. While we currently have a depression screening and follow-up measure in the GPRO WI, the Depression Remission measure represents an important outcome. Depression management is particularly important due the effects on patient adherence with treatment for other chronic conditions.	MNCM	MU2

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Please note that, if these proposals are finalized, the GPRO measure set will contain 21 measures available for reporting.

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 note 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 indicate in Table 21, we are proposing to reclassify the CAHPS for PQRS survey under the Person and Caregiver-Centered Experience and Outcomes domain. We invite public comment on this proposal.

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 are not proposing to remove any of the requirements we finalized related to these parameters, we are proposing 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:

• 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 are proposing 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 are modifying this requirement to conform to this proposed satisfactory participation criterion. Therefore, we are proposing 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.

We are proposing to define resource use, patient experience of care, or efficiency/appropriate use measures in the following manner:

• 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.

• 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.

• 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.

Please note that, for purposes of meeting the criteria for satisfactory participation in a QCDR, we allow QCDRs to report on any measure provided that it meets the measure parameters we finalize. We note 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 propose 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 propose 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 aide in creating transparency of reporting.

We invite public comment on these proposals.

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 propose 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) are 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 propose to revise § 414.90(m)(1).

Regarding the eligible professional's or group practice's ability to provide additional information to assist in the informal review process, we propose to provide the following limitations as to what information may be taken into consideration:

• CMS would only allow resubmission of data that was submitted using a third-party vendor using either

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 are proposing 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 invite public comment on these proposals.

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. While 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 are proposing 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). When establishing this requirement, we did not account for instances where errors are discovered in the updated electronic measure specifications. To account for these instances and consistent with the proposal set forth in the PQRS in section III.K, we propose that, beginning in CY 2015, if we discover 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.

Additionally, we noted 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 (78 FR 74757). 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). Since 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 propose 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 propose 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 encourage 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 invite public comment on this proposal.

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 (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, 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). We have identified several policies related to the quality performance standard that we would like to address in this rule at this time. Specifically, we are revisiting the current quality performance standard, proposing changes to the quality measures, and seeking comment on future quality performance measures. We are also proposing 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) 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. For example, we issued the specifications for the 2014 reporting period in late 2013, prior to the start of the 2014 reporting period.

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. Proposed Changes to the Quality Measures Used in Establishing Quality Performance Standards That ACOs Must Meet To Be Eligible for Shared Savings

Since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and are aligned with the GPRO web interface reporting for PQRS. Based on the reviews, we have identified a number of proposed measure additions, deletions and other revisions that we believe would be appropriate for the Shared Savings Program. Under the following proposed measure revisions, ACOs would be assessed on 37 measures annually, an increase of 4 measures. However, as explained in more detail below, we believe the measures chosen are more outcome-oriented and would ultimately reduce the reporting burden on ACOs.

The following is a description of the proposed changes that would be effective for the 2015 reporting period and would be reported by ACOs to us in early 2016. Table 50 offers an overview of the proposed changes and is provided as a reference. (We note that the deletion and insertion of certain measures affects the composite measures, and we are proposing corresponding revisions to both the diabetes and coronary artery disease composite measures.)

• *CAHPS Stewardship of Patient Resources.* This measure is one of the unscored survey measures currently collected in addition to the seven that are already part of the current set of 33 scored 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 was important to them. We are proposing 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 experience with healthcare providers. We are also proposing 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 measure modules in the survey that are currently used to assess ACO quality performance. We seek comment on this proposal and on any other patient experience of care measures that might be considered in future rulemaking.

• *Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).* We propose to add a 30-day all cause 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 Skilled Nursing Facility 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 providers/suppliers often include post-acute care (PAC) settings and the addition of this measure would enhance the participation 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 is calculated from claims, there would not be a burden on ACOs to collect this information.

• *All-Cause Unplanned Admissions for Patients with Diabetes Mellitus (DM), Heart Failure (HF) and Multiple Chronic Conditions.* We propose to add three new measures to the Care Coordination/Patient Safety domain. The three proposed 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. These three measures are under development though 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 they are major causes for unplanned admissions and 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.

• *Depression Remission at Twelve Months.* We propose to add Depression Remission at Twelve Months (NQF #0710) to the Preventive Health domain. Depression is a serious health condition for the Medicare population and can decrease patient adherence to treatment for chronic conditions. This measure would enhance our measurement of health outcomes and depression is an important health condition that we believe is appropriate to be addressed by ACOs. The measure would be submitted through the GPRO web interface, and would be aligned with PQRS. We also seek comments on the inclusion of additional behavioral health measures, such as substance abuse or mental health measures, in future rulemaking cycles.

• *Diabetes Measures for Foot Exam and Eye Exam.* Diabetes is one of the most serious, chronic health conditions for Medicare beneficiaries. It is critical that Medicare beneficiaries that have diabetes receive foot and eye exams to help prevent diabetes-related foot amputations and blindness. Both of the two new measures would be added to the Clinical Care for at Risk Population-Diabetes domain. They are endorsed by NQF (NQF #0055 and #0056). We also propose to include these two new measures as part of a new Diabetes Mellitus composite measure. These measures would also align with PQRS and the EHR Incentive Program. We believe these measures would be

appropriate additional measures for assessing quality of care furnished in ACOs to help prevent diabetes-related foot amputations and blindness.

• *Coronary Artery Disease (CAD): Symptom Management.* This new measure would be added to the Clinical Care for At Risk Population-Coronary Artery Disease domain and included in the CAD Composite Measure. The measure helps assess symptom management for CAD patients based on the percentage of adults 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. This new measure would be added to further enhance the CAD composite measure by adding an assessment of patient activity level and management of angina, which are important clinical factors for beneficiaries with CAD. The measure would align with PQRS (PQRS #0242) and the EHR Incentive Program.

• *Coronary Artery Disease (CAD): Beta Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF<40%).* This new measure would be added to the Clinical Care for At Risk Population-Coronary Artery Disease domain and included in the CAD Composite Measure. This new measure is endorsed by NQF as NQF #0070 and would be added to further enhance the CAD composite measure. This measure reflects the number of patients with CAD who have prior myocardial infarction or LVEF <40 percent who are prescribed beta-blocker therapy and thus is designed to support improvement in outcomes for these CAD patients.

• *Coronary Artery Disease (CAD): Antiplatelet Therapy.* This new measure would be added to the Clinical Care for At Risk Population-Coronary Artery Disease domain and included in the CAD Composite Measure. The measure is defined as the percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period that were prescribed aspirin or clopidogrel. This new measure is endorsed by NQF as NQF #0067 and would be added to update the CAD composite measure to reflect updated clinical guidelines for lipid control. This new measure would replace the existing measure at ACO #30, Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic, which we are proposing to remove because it no longer reflects current clinical guidelines.

• *Documentation of Current Medications in the Medical Record (NQF #0419).* This new measure would replace ACO #12 (NQF #0097) Medication Reconciliation measure. The current measure is designed to determine whether medication reconciliation was done immediately following a hospital discharge whereas the medical community has indicated to us that it is better clinical practice to perform medication reconciliation at every office visit, which NQF #0419 is designed to measure. In addition, this new replacement measure aligns with both PQRS and the EHR Incentive Program.

• *Percent of PCPs who Successfully Meet Meaningful Use Requirements.* Because the EHR Incentive Program begins its transition to a payment adjustment effective in 2015, we propose 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.

We seek comment on these proposed new measures.

Additionally, we have identified a number of the existing measures that have not kept up with clinical best practice, are redundant with other measures that make up the quality reporting standard, or that could be replaced by similar measures that are more appropriate for ACO quality reporting. We propose 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 qualify to share in savings:

• *ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility:* As explained above, we would replace this measure with a new measure for documentation of current medications in the medical record since the medical community has indicated the importance of medication reconciliation at each office visit rather than only after an inpatient discharge.

• ACO #22, *Diabetes Composite measure: Hemoglobin A1c control (<8 percent).* The Hemoglobin A1c Control (<8%) component is being proposed for removal as we have concerns that the HbA1c level monitored in this measure is considered too low to comprehensively evaluate HbA1c control for the frail elderly population.

• ACO #24, *Diabetes Composite: Blood Pressure (<140/90) (NQF #0729).* In an effort to reduce redundant and burdensome ACO reporting of quality measures, we are proposing to no longer collect data for this measure. Although we recognize that the sample patient populations for the measures are different, we believe that there is clinical overlap between ACO #24 and ACO #28, Hypertension (HTN): Blood Pressure Control (NQF #0018). We propose to retain ACO #28, rather than ACO #24, because ACO #28 represents a more comprehensive assessment of an ACO's performance in controlling its population's high blood pressure, whereas the diabetes measure assesses a subpopulation of the broader blood pressure measure.

• ACO #25, *Diabetes Composite: Tobacco Non-use (NQF #0729).* We believe this measure is somewhat duplicative of the separate measure ACO #17, Tobacco Use Assessment and Tobacco Cessation Intervention (NQF #0028) and that the diabetes measure may capture a subpopulation of the broader measure. We prefer to use NQF #0028 as a measure of tobacco use for the Shared Savings Program because this measure has been identified as a cross-cutting measure as it represents a screening assessment that most eligible professionals may perform and is applicable to most adult patients. This measure is applicable in various outpatient settings.

• ACO #23, *Diabetes Composite: Low Density Lipoprotein (<100) (NQF #0729).* We propose to retire this and the two other lipid control measures listed below as a result of new clinical guidelines released in 2013 by the American College of Cardiology and American Heart Association (see *https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf*). The new guidelines recommend treating individuals with moderate-to-high dose statin therapy based on cardiac risk rather than only treating high cholesterol to specific targets.

• ACO #29, *Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100 mg/dl) (NQF #0075).* We propose to retire this lipid control related measure because of the new clinical guidelines for statin treatment as noted in the previous bullet.

• ACO #30, *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068).* This measure would be replaced by the proposed new CAD measure for antiplatelet therapy (NQF #67), which reflects current clinical guidelines.

• ACO #32, *Coronary Artery Disease (CAD) Composite: Drug Therapy for Lowering LDL Cholesterol (NQF #74).*

We propose to retire this lipid control related measure because of the new clinical guidelines for statin treatment as noted above.

We seek comment on our proposal to remove these measures from the quality performance standards.

Finally, given these proposed changes, we propose updates and revisions to the Diabetes and CAD Composites. We propose that the Diabetes Composite would 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 propose that the CAD Composite would 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 seek comment on these proposed composites and whether there are any concerns regarding calculation of a composite score. There has been increased interest in the use of composite performance measures over the past few years and stakeholders have raised general concerns regarding composite measures and their purpose for quality improvement. CMS worked with the National Quality Forum (NQF) and their technical expert panel in 2013 to update NQF's composite measure evaluation guidance, which in turn may also be used by developers for composite measure development. Given the general concerns around composite measures and their use, we seek comment on how we combine and incorporate component measure scoring for the composite. In particular, we are interested in whether stakeholders have any concerns about including ACO #27, reverse-scored measure, in the Diabetes Composite, and whether there are any methodological considerations we should consider when including a reverse-scored measures in composites.

To summarize, under these proposed changes, we would add 12 new measures and retire eight measures. We are also proposing 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 propose to use 37 measures for establishing the quality performance standards that ACOs must meet to achieve shared savings. Although the total number of measures would increase from the current 33 measures to 37 measures, we do not anticipate that this would increase the reporting burden on ACOs. 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 Web site interface would actually decrease by one, in addition to removing redundancy in measures reported.

As part of these proposed changes, we would replace the current five component diabetes composite measure with a new four component diabetes composite measure. In addition, we would replace the current two component coronary artery disease composite measure with a new four component coronary artery disease composite measure. Twenty-one of the measures would be reported by ACOs through the GPRO web interface and scored as 15 measures.

An overview of the proposed changes is provided in Table 50 which demonstrates what measures would be used to assess ACO quality under the Shared Savings Program if our proposals are finalized.

TABLE 50—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS

Domain	ACO Measure No.	Measure title	Proposed new measure	NQF No./ 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

TABLE 50—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO Measure No.	Measure title	Proposed new measure	NQF No./ Measure steward	Method of data submission	Pay for performance phase in R—Reporting P—Performance		
						PY1	PY2	PY3
	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
	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	P	P
Clinical Care for At Risk Population—Diabetes.		Diabetes Composite (All or Nothing Scoring).		CMS composite	CMS Web Interface.	R	P	P

TABLE 50—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO Measure No.	Measure title	Proposed new measure	NQF No./ Measure steward	Method of data submission	Pay for performance phase in R—Reporting P—Performance		
						PY1	PY2	PY3
	ACO–26	ACO–26: Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease.	.....	NQF #0729 MNCN (individual measure).	.....	R	P	P
	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: Foot Exam	X	NQF #0056 NCQA (individual component).	CMS Web Interface.	R	P	P
	ACO–42	ACO–42: 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—Heart Failure.	ACO–31	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	.....	NQF #0083 AMA–PCPI.	CMS Web Interface.	R	R	P
Clinical Care for At Risk Population—Coronary Artery Disease.	.....	Coronary Artery Disease (CAD) Composite (All or Nothing Scoring).	.....	CMS composite	CMS Web Interface.	R	R	P
	ACO–33	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 (individual component).	CMS Web Interface.	R	P	P
	ACO–43	ACO–43: Antiplatelet Therapy.	X	NQF #0067 ACC (individual component).	CMS Web Interface.	R	R	P
	ACO–44	ACO–44 :Symptom Management.	X	NQF #N/A AMA–PCPI (individual component).	CMS Web Interface.	R	R	P
	ACO–45	ACO–45: Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%).	X	NQF #0070 ACC (individual component).	CMS Web Interface.	R	R	P

Table 51 provides the current number of measures by domain and displays the total points and domain weights used for scoring purposes. The current 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). Table 52 provides a summary of the proposed number of measures by domain and the resulting total points and domain weights that would be used for scoring purposes under these proposed changes. Otherwise, the current quality scoring points methodology for calculating an ACO's overall quality performance score would continue to apply. Table 53 provides the measures that are retired/replaced.

TABLE 51—CURRENT NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	7	7 individual survey module measures	14	25
Care Coordination/Patient Safety	6	6 measures, including the EHR measure double-weighted (4 points).	14	25
Preventive Health	8	8 measures	16	25
At-Risk Population	12	7 measures, including 5-component diabetes composite measure and 2-component coronary artery disease composite measure.	14	25
Total in all Domains	33	28	58	100

TABLE 52—PROPOSED NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety	10	9 measures, plus the EHR measure double-weighted (4 points).	22	25
Preventive Health	8	8 measures	16	25
At-Risk Population	11	5 measures, including 3 individual measures plus a 4-component diabetes composite measure and a 4-component coronary artery disease composite measure.	10	25
Total in all Domains	37	31	64	100

TABLE 53—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 Year 1	Performance Year 2	Performance 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

TABLE 53—SHARED SAVINGS PROGRAM MEASURES RETIRED/REPLACED—Continued

Notes	Domain	Measure title	NQF measure #/ measure steward	Method of data submission	Pay for Performance Phase In R = Reporting P=Performance		
					Performance Year 1	Performance Year 2	Performance Year 3
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 #30 Replaced.	At Risk Population—Ischemic Vascular Disease.	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.	NQF #68 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 will enhance ACO quality reporting, better reflect clinical practice guidelines, streamline measures reporting, and enhance alignment with PQRS and the EHR Incentive Program. Finally, we are proposing that these measures would become effective beginning with the 2015 reporting period, and 2015 performance year (PY). All 37 measures would be phased in for ACOs with 2015 start dates according to the phase-in schedule in Table 50. 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 the measures according to the phase in schedule. 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, the ACO would be responsible for complete and accurate reporting of the new measure in PY2 and for performance on the measure in PY3. If we change the assumptions in the example to say that the new measure is scheduled to phase in with reporting in PY1, performance in PY2, and performance in PY3, then the ACO would be responsible for complete and accurate reporting of the new measure in PY2 and for performance on the measure in PY3. Finally, we note that consistent with our proposed revisions to § 425.502(a) regarding quality reporting in a second and subsequent agreement period, an ACO that transitions to a new agreement period would continue to be assessed on the quality performance standard that would otherwise apply to an ACO in the third performance year of its first agreement period. Take the example of an ACO with a 2013 start date that will be responsible for reporting the new measure in the 2015 reporting period, its third performance year. Assume the measure is scheduled to phase in from reporting in PY1, reporting in PY2, and performance in PY3. In this case, the ACO would be responsible for complete and accurate reporting of the new measure in 2015 (PY3 of its first agreement period). If the ACO renews its participation agreement for another 3 years, the ACO would be responsible for performance on that measure for each year of its new agreement period because the measure is designated as a pay for performance measure in PY3 of the preceding agreement period.

Additionally, 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. To the extent that PQRS modifies and finalizes changes in the reporting requirements for group practices reporting via the GPRO web interface, we propose to make similar modifications to ACO reporting through the GPRO web interface. Specifically, as discussed in section III.K.4.a. of this proposed rule, we are proposing 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 propose that the reduced sample for each measure for reporting through the GPRO web interface would also apply to ACOs. 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.

3. Request for Comments for Future Quality Measures

In addition to the proposed changes to the current set of 33 quality measures for the Shared Savings Program discussed above, we are interested in public comment on additional measures that we may consider in future rulemaking. We particularly welcome comments regarding the following issues:

• *Gaps in measures and additional specific measures:* We recognize that there may be gaps in the ACO quality performance standard. For example,

ACOs are charged with improving care coordination for FFS beneficiaries. While above we propose to add a measure for SNF 30-day all-cause readmission to address current gaps in SNF settings, we seek comment on whether there are additional measures that might be used to assess the ACO's performance with respect to care coordination in post-acute care and other settings. We also recognize the need to balance filling gaps in the quality performance standard with the reporting burden on ACOs. To the extent possible, we wish to identify measures for filling any gaps in the quality performance standard that would not increase the reporting burden on ACOs unduly. We welcome 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. For example, we seek input on measures that address the quality of care in the various different settings that may be part of an ACO, such as post-acute care settings including SNF or home health. We note that any suggestions for new measures would be more thoroughly discussed in a future rulemaking cycle prior to being adopted as part of the quality performance standard under the Shared Savings Program and if we deem it appropriate we would also submit them to the NQF Measures Application Partnership (MAP) via the list of Measures Under Consideration that the Secretary annually makes available to the public as part of the pre-rulemaking process under section 1890A(a)(2) of the Act for the purpose of seeking multi-stakeholder group input, consistent with the requirements of section 3014 of the Affordable Care Act, if the measures have not already been reviewed by the MAP.

• *Caregiver experience of care:* While we recognize there is a concern about patient subjectivity to surveys, we include measures based on data collected via the patient experience of care survey in the quality performance standard because we believe patients' perception of their care experience reflects important aspects of the quality of the care they receive, such as communication and patient engagement in decision-making, that are not adequately captured by other measures. As such, patient surveys are important complements to the other process of care and outcomes measures. For this reason, we stated in November 2011 Shared Savings Program final rule (76 FR 67874) that we intended to expand the quality measures over time to include more caregiver experience measures. Therefore, we seek 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 desire to continue to align with other Medicare quality initiatives in order to reduce ACO burden and streamline quality reporting and indicators. In the CY 2013 PFS final rule with comment period (77 FR 69313) we established a policy not to apply the VM in CY 2015 and CY 2016 to groups of physicians that participate in ACOs under the Shared Savings Program. Although section 1848(p)(4)(B)(iii)(I) of the Act gives the Secretary discretion to apply the VM to specific physicians and groups of physicians as the Secretary determines appropriate for 2015 and 2016, consistent with section 1848(p)(4)(B)(iii)(II), which requires application of the VM to all physicians and groups of physicians beginning not later than January 1, 2017, we are proposing to start applying the VM to physicians participating in ACOs beginning in 2017. In addition, in section III.K.4.b of this proposed rule, we discuss our proposal to also apply the VM to all nonphysician eligible professionals in groups with 2 or more eligible professionals and to solo practitioners who are nonphysician eligible professionals, including eligible professionals participating in ACOs, starting in CY 2017. To that end, we are seeking comment on whether there are synergies that can be created by aligning the ACO quality measures set with the measures used under the VM. For example, in the Value-based Modifier program, there are two claims-based composite outcomes measures, namely, the Composite of Acute Prevention Quality Indicators (PQIs) comprised by 3 measures (NQF #279 Bacterial Pneumonia Admission Rate, NQF #280 Dehydration Admission Rate, and NQF #281 Urinary Tract Infection Admission Rate) and the Composite of Chronic Prevention Quality Indicators (PQIs) comprised by 6 measures (NQF #638 Uncontrolled Diabetes, NQF #272 Short Term Diabetes complications, NQF #274 Long Term Diabetes Complications, NQF #285 Lower Extremity Amputation for Diabetes, NQF #275 COPD, and NQF #277 Congestive Heart Failure). (See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2012–ACSC-Outcomes-Msrs.pdf*). Because these VM measures are claims based measures, no additional reporting burden would be added to ACOs. In addition, we note that two of these measures are currently a part of the ACO quality measures set, specifically, NQF #275, ''Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease,'' and NQF #277: ''Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure.'' Although we are not proposing changes at this time to align with the measures used under the VM, we are seeking 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 recognize providers face challenges in caring for the health needs of the frail elderly. There are, however, many challenges in defining and measuring the quality of care for this population. In the November 2011 Shared Savings Program final rule, we incorporated a measure focused on the frail elderly population—ACO#13 Screening for Fall Risk, which rewards ACOs for incorporating fall risk assessments in the redesign of their care processes. Our expectation was that practitioners would use the results of the fall risk assessments to promote meaningful conversations with their frail elderly patients about fall risks and ways to prevent or reduce these events. We also stated that as ACOs gain more experience integrating the fall risk screening into their day-to-day practices, we planned to revisit the frail elderly measures in future rulemaking to build upon these achievements and to address additional issues for the frail elderly (76 FR 67886). We welcome 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 did not include utilization measures in the quality performance standards adopted in the November 2011 final rule establishing the Shared Savings Program because we believed that ACOs have an intrinsic motivation to reduce inappropriate utilization of services in order to achieve shared savings. However, in recognition of the value of feedback on utilization, we include utilization data as part of the quarterly aggregate reports provided to ACOs. We welcome comments on whether it is sufficient for such 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 are interested in having such utilization measures included in the quality performance standard, we welcome specific comments on what measures would be most appropriate and suggestions for how to risk adjust these measures.

• *Health outcomes:* Currently, the quality performance standard includes a self-reported health and functional status measure as part of the patient experience of care survey. We finalized this measure as pay for reporting for all 3-years of the agreement period to allow ACOs to gain experience with the measure (which had not previously been used for accountability purposes in any pay-for-performance initiative) and to provide important information to them on improving the health outcomes of the population they serve (76 FR 67876). Patient-reported outcomes, although subjective, provide valuable information not captured by other means. We continue to believe that it is appropriate to require ACOs to report this measure and to maintain the performance standard at full and accurate reporting in order to allow ACOs to gain experience with the measure. We welcome 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 welcome 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. This survey would require at least 2 years of reporting by the same beneficiary and assesses function over time rather than function at a particular point in time. We also welcome suggestions for alternatives to self-reported measures that may be considered in the future.

• *Measures for retirement:* Some measures may not provide sufficiently useful information for assessing ACO quality performance since they are ''topped out'', meaning that all but a very few of organizations achieve near perfect performance on the measure. As a result, such measures may no longer provide meaningful information regarding an ACO's quality performance. Other examples of candidates for retirement could be measures that do not drive quality improvement. We seek input from commenters on any measures that should be considered for retirement in future rulemaking. We welcome comments on whether to continue to require ''topped out'' measures be included as pay for reporting measures. For example, it could be important to require ACOs to continue to report such measures so that we can assess performance to ensure quality of care does not decline or for other reasons. In addition, we note that as discussed below we are proposing changes to the benchmarking methodology for topped out measures.

• *Additional public health measures:* 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 are 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 welcome comments on the potential addition of this measure and would consider any comments received in developing any future proposal with respect to this measure.

4. Accelerating Health Information Technology

a. Overview

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their 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.'' *http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie*). The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives including: (1) alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT 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 networks. 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, as well as those providers that are participating in the Medicare Shared Savings Program in an ACO and those that are not, 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 IT's (ONC's) HIT Certification Program and expand HIT certification, ONC has issued a proposed rule concerning a voluntary 2015 Edition of EHR certification criteria, which would more easily accommodate certification of HIT for technology used in health care settings where health care providers are not typically eligible for incentive payments under the EHR Incentive Programs, to facilitate greater HIE across the entire care continuum.

We believe that HIE and the use of certified EHRs can effectively and efficiently help ACOs and participating providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of eCQMs. More information on the Voluntary 2015 Edition EHR Certification Criteria Proposed Rule is available at *http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations*.

b. 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. Adoption of certified EHR technology (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 certified EHR technology 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 proposing to revise the name and the specifications for the quality measure regarding EHR adoption to take the changing incentives into account. Specifically, we are proposing to change 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 clarify 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 web interface measures and satisfy the reporting requirements under the Shared Savings Program in order for 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 propose 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. This new paragraph will 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 GPRO quality reporting requirements from CEHRT; and (2) the ACO satisfactorily reports the ACO GPRO measures through a CMS Web interface. Although this proposal 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.

We recognize there are operational constraints that must be considered when developing policies related to electronic reporting of quality measures under the Shared Savings Program. First, many ACO legal entities are conveners of Medicare enrolled entities, but are not Medicare-enrolled themselves, that is, many ACO legal entities do not provide direct health care services, and therefore, may not thus far have had a need for an EHR. Further, ACO participants and ACO providers/suppliers may be at different levels of EHR adoption. For example, an ACO may have ACO participants that do not own an EHR. Other ACOs may have ACO participants that have and use EHR platforms, but have chosen different platforms, each requiring different modifications to make them uniformly extract required quality data. In addition, ACOs have told us that different EHR platforms may not yet be seamlessly interoperable. Finally, within each ACO participant, there may be differing levels of EHR use among the ACO providers/suppliers that are EPs. Operationally, a few options could be considered for implementing the eCQM portion of the meaningful use requirements in the future. For example, we could consider whether it would be preferable for the EPs within each ACO participant to individually submit EHR data to CMS, whether each ACO participant should report as a group; whether the ACO itself should aggregate EHR data from its ACO participants and then submit the quality measures to CMS; or whether the ACO could submit quality measure data via a data submission vendor that would be responsible for aggregating and submitting the data on the ACO's behalf.

Although we are not proposing any new requirements regarding EHR based reporting under the Shared Savings Program at this time, we welcome suggestions and comments about these issues which we would consider in developing any future proposals. We especially seek 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 are interested in the opportunities and barriers to ACO EHR quality measure reporting, as well as ways to overcome any barriers. We also welcome 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 seek 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 seek 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.

3. 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 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. Proposed Revisions for Benchmarking Measures That Are ''Topped Out''

In the discussion of measures above, we indicated that some measures may be topped out, meaning that all but a very few of 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 are proposing 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 propose to revise § 425.502(b)(2)(ii) to reflect this proposed policy. We invite comments on this proposal. We also invite comments on other potential approaches for addressing topped out measures. We would use any comments received to help develop any future proposals regarding topped out measures. For example, we welcome 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.

c. Proposed 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 propose 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. As proposed earlier in this section, new measures that are added to the quality performance standard would be phased in along the timeline indicated when the measure is added and in operational documents.

d. Proposed 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 benchmarks are 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 propose 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 propose to revise § 425.502(b) to add a new paragraph (b)(4)(i), which will 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 54. 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 propose to revise § 425.502(b) to add a new paragraph (b)(4)(ii), which will 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 seek comment on this proposal. We specifically seek comment on the appropriate number of years that a benchmark should remain stable before it is updated. We also welcome 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 are proposing to retain our current policy of using the most recent available data to set the quality performance benchmarks, we also seek comment on whether data from other reporting periods should also be considered in establishing benchmarks that will apply for 2 performance years. Specifically, we seek 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?

TABLE 54—PROPOSED TIMELINE FOR SETTING AND UPDATING QUALITY PERFORMANCE BENCHMARKS

Reporting period for data used to set benchmark	Year data is collected, analyzed, and benchmark is published	Performance year and reporting period to which benchmark applies
2012	2013	2014 & 2015
2014	2015	2016 & 2017
2016	2017	2018 & 2019

4. 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 proposed previously.

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 proposal discussed above in which we propose to 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 are 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. The success of the Shared Savings Program is partially dependent on ACOs further improving the quality of the care they provide, not merely maintaining current levels of quality. Therefore, we are proposing 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. We believe that offering an additional and explicit reward for improving quality performance 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.

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 performance year minus the score in 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 believe is 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 Web site 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 propose 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 would 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 can be achieved in a domain, including up to 2 bonus points, could not exceed the current maximum total points achievable within the domain. For example, as shown in Table 51, currently the total possible points for the patient/caregiver experience domain, which has seven individual measures, is 14 total possible points. Under this proposal to provide for quality improvement bonus points, the maximum possible points within this domain would continue to be 14. If an ACO scored 12 points and was awarded two additional bonus points for quality improvement then the ACO's total points for this domain would be 14. However, if instead this same ACO had scored 13 points, then this ACO's total points after adding the bonus points could still not exceed 14.

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 follow:

Table 51 shows the maximum possible points that currently may be earned by an ACO in each domain and for all domains. Table 52 shows the maximum possible points that may be earned under the proposed quality measures changes. The data in Tables 51 and 52 are not affected by this proposal to provide for bonus points for quality improvement and do not include the proposed maximum of two bonus points in each domain. 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. We believe it would be appropriate to include pay-for-reporting measures for purposes of determining quality improvement and

awarding bonus points since under § 425.500(f) ACOs that fail to report all quality measures, including pay-for-reporting measures completely, accurately, and timely may be subject to termination or other corrective action. As an example, pay for reporting applies to the CAHPS health status/functional status measure for all three performance years. However, the ACO's performance on the health status/functional status measure would still be considered in performance years two and three when we evaluate whether an ACO should be awarded bonus points.

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 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 Web site 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. 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 two bonus points would be awarded on a sliding scale based on the ACO's net improvement for the domain to the total number of individual measures in the domain. Specifically, the bonus points, up to a maximum of 2 points, would 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 seven individual measures for the patient/caregiver experience of care domain. If the ACO achieved a significant quality increase in all seven measures then the ACO would be awarded the maximum of two bonus points for this domain. However, if the ACO achieved a significant quality increase in only one of the seven measures in this domain and no significant quality decline on any of the measures then the ACO would be awarded 0.29 bonus points for quality improvement in the domain that is 1/7 times 2 = 0.29. The total points that the ACO could achieve in this domain could still not exceed the current maximum of 14 points shown in Table 51.

Tables 51 and 52 reflect the current quality measure scoring methodology which would continue under this proposal. These tables show the number of points available per domain under both the current quality performance standard and the proposed revisions to the quality performance standard.

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, 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 savings it shares 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 are not proposing that option because we are 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 have some concerns about whether it would be appropriate to use the ''pay for reporting'' data reported to us, given that the accuracy does not affect an ACO's quality performance score in the first performance year. Therefore, we considered whether the proposed 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 are proposing to add a new paragraph (e)(4) to § 425.502 to incorporate this proposed process for calculating bonus points for quality improvement into the quality performance scoring methodology. We seek comments on this proposal and welcome comments on the alternative approaches discussed above. We also seek 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 welcome 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.

5. 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, propose to make a technical correction to § 425.502(d)(2)(ii) to eliminate the specific reference to paragraph (c) of § 425.216. We also propose to correct a typographical error in this provision by revising ''actions describe'' to read ''actions described.''

In addition, we are also proposing 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 propose 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 request comments on these proposed technical corrections.

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.

In this rule, we are proposing policies to apply the VM to all physicians and groups of physicians and also nonphysician eligible professionals and to increase the amount of payment at risk. We also are proposing to refine the methodologies used to determine our quality and cost composites and also to establish a corrections process for 2015.

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 Quality Strategy and other CMS quality initiatives, including the PQRS, the Shared Savings Program, and the Medicare EHR Incentive Program.
- *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 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 starting January 1, 2015, to payments under the Medicare PFS for 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 2013 PFS proposed rule (77 FR 44991 through 45021). Similarly, in the CY 2014 PFS final rule with comment period, we finalized policies to phase-in 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. The policies that we finalized for the CY 2016 VM can be found in the CY 2014 final rule with comment period (78 FR 74765 through 74787).

4. Provisions of This Proposed Rule

We are making the following proposals regarding the VM policies:

- To apply the VM to all physicians and nonphysician eligible professionals in groups with 2 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. Category 1 includes: (1) Groups that meet the criteria for satisfactory reporting of data on PQRS quality measures via the group practice reporting option (GPRO) for the CY 2017 PQRS payment adjustment; (2) 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 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; and (3) solo practitioners that meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals 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. However, groups with between 2 and 9 eligible professionals and solo practitioners would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology, and groups with 10 or more eligible professionals would be subject to upward, neutral, or downward adjustments determined under the quality-tiering methodology.
- To apply the VM to physicians and nonphysician eligible professionals participating in the 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.

We also seek comment on, but make no proposals regarding the treatment of hospital-based physicians with regard to the VM.

a. Group Size

Section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the VM 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.

In the CY 2013 PFS final rule with comment period, we stated that we would gradually phase in the VM in CY 2015 by first applying it to large groups (77 FR 69308), which we defined as groups of physicians with 100 or more eligible professionals. In the CY 2014 PFS final rule with comment period, we continued our phase-in of the VM and adopted a policy to apply the VM in CY 2016 to groups of physicians with 10 or more eligible professionals (78 FR 74765–74767).

As mentioned above, 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 propose to apply the VM in CY 2017 and each subsequent calendar year payment adjustment period to physicians in groups of physicians with 2 or more eligible professionals and to physicians who are solo practitioners. 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 propose to define a ''solo practitioner'' at § 414.1205 as a single Tax Identification Number (TIN) with 1 eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN. This proposal completes our phase in of the VM as required by the Act. Please note that in section III.N.4.b of this proposed rule, we discuss our proposal to also apply the VM to nonphysician eligible professionals in groups subject to the VM and to nonphysician eligible professionals who are solo practitioners in CY 2017 and subsequent CY payment adjustment periods. Additionally, we note that in section III.N.4.g of this proposed rule, we state 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.

Table 55 shows 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. 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 our proposals to apply the VM to all groups with 2 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) that consist of approximately 815,000 physicians and 315,000 nonphysician eligible professionals.

TABLE 55—ELIGIBLE PROFESSIONAL/PHYSICIAN GROUP SIZE DISTRIBUTION (2012 CLAIMS)

Group size	Number of groups (TINs)*	Eligible professionals (EPs)	Number of physicians	Number of non-physician EPs	Percent of physicians	Percent of non-physician EPs
100+ EPs	1,044	303,009	223,917	79,092	27	25
50–99 EPs	1,526	103,998	71,089	32,909	9	10
25–49 EPs	3,675	125,314	85,127	40,187	10	13
20–24 EPs	1,831	39,887	27,115	12,772	3	4
10–19 EPs	8,356	112,553	76,905	35,648	9	11
2–9 EPs	67,065	235,756	166807	68,949	20	22
1 EP	209,950	209,950	164,334	45,616	20	14
Total	293,447	1,130,467	815,294	315,173	100	100

*The number of groups (TINs) does not include TINs that have one or more EPs participating in the Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative.

As discussed in the CY 2014 PFS proposed rule with comment period (78 FR 43500 through 43502), we conducted statistical reliability analysis on the PQRS quality measures contained in the 2010 and 2011 group and individual Quality and Resource Use Reports (QRURs). These reports contained the PQRS quality measures used in these years, and these PQRS measures are similar to the PQRS measures that will be used in the VM starting in CY 2015. The quality measures in the group reports were statistically reliable at a high level. Moreover, at that time, the average reliability score was high for 98 percent of the individually reported PQRS measures included in the individual feedback reports; therefore, with the exceptions discussed in section III.N.4.h of this proposed rule regarding the all cause hospital readmission measure, we believe that the PQRS quality measures for groups with 2 or more eligible professionals and solo practitioners will also be reliable since they are chosen by the physicians and reflect their patients' conditions and practices' clinical priorities.

We believe that we can validly and reliably apply a VM to groups with 2 or more eligible professionals and to solo practitioners because we would 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. We believe that the VM should recognize the diversity of medical practices and the various measures used to assess quality of care furnished by these practices and provide flexibility on the data they report for quality measures under the PQRS. Therefore, beginning in the CY 2014 performance period for the groups of physicians subject to the CY 2016 VM, we have permitted these groups for purposes of the VM to participate in the PQRS as a group under the GPRO or to have at least 50 percent of the eligible professionals in the group participate in the PQRS as individuals (78 FR 74767 through 74768). As a result, physicians and other eligible professionals in the group are able to report data on quality measures that reflect their own clinical practice. In the latter case, as proposed in section III.N.4.c of this proposed rule, a group would be included in Category 1 (as described in section III.N.4.c of this proposed rule) if at least 50 percent of the eligible professionals in the group meet the criteria to avoid the CY 2017 PQRS payment adjustment by using any of the reporting options available to them under the PQRS in CY 2015.

We also conducted statistical reliability analyses on the cost measures contained in the 2010 and 2011 group and individual QRURs. These reports contained the same 5 per capita cost measures that will be used for the VM. The cost measures in the group reports were statistically reliable at a high level, and the average reliability score was high for all of the cost measures included in the individual feedback reports. In addition, as discussed in the CY 2014 PFS final rule with comment period (78 FR 74774–74784), we are including the Medicare Spending per Beneficiary (MSPB) measure in the cost composite of the VM and are adjusting the cost comparison approach to consider the medical specialty composition of the group of physicians. Based on an analysis of CY 2012 claims, we estimate that approximately 48 percent of all eligible professionals are in a group (as identified by a TIN) that would have the total per capita cost measure, as identified in § 414.1235(a)(1), in its cost composite score; approximately 41 percent of all eligible professionals are in a TIN that would have the MSPB measure in its cost composite score; and approximately 34 percent of all eligible professionals are in a TIN that would have both measures in its cost composite score. Therefore, we believe that we will be able to calculate a cost composite score for a significant number of groups and solo practitioners. 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 note 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 believe the regulation text at § 414.1270(b)(5) better reflects the intent of this policy, and accordingly, we propose 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 propose 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 propose to revise § 414.1270 accordingly.

We believe we have provided smaller groups and solo practitioners sufficient lead time to understand how the VM works and how to participate in the PQRS. In the late summer of 2014, we plan to disseminate QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. These QRURs will 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. 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. Then, during the summer of 2015, we intend to disseminate QRURs based on CY 2014 data to all groups of physicians and physicians who are 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. Thus, we believe all groups and solo practitioners will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. Although we are sensitive to providing groups and solo practitioners with adequate lead time to understand the impact of the beneficiary attribution method used for the VM, we believe our proposal to hold harmless groups with between 2 and 9 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 proposed rule).

Accordingly, we propose to revise the regulations at § 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 2 or more eligible professionals and to solo practitioners based on the performance period described at § 414.1215. As established in the CY 2014 PFS final rule with comment period (78 FR 74772) and stated in section III.N.4.g of this proposed rule, CY 2015 is the performance period for the CY 2017 VM. Since the VM policies established for the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period would apply to groups and solo practitioners, we propose to amend the regulations under subpart N to add references to solo practitioners accordingly. We seek comments on all of these proposals.

b. Application of the VM to Nonphysician EPs

Section 1848(p) of the Act requires that we establish a 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. In CY 2015 and CY 2016, we apply the VM to the 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. 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 proposed rule, we discussed 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 2 or more eligible professionals and to physicians who are solo practitioners as required by section 1848(p)(4)(B)(iii)(II) of the Act.

Under the discretion afforded the Secretary in section 1848(p)(7) of the Act, we propose to apply the VM beginning in the CY 2017 payment adjustment period to all of the eligible professionals in groups with 2 or more eligible professionals and to eligible professionals who are solo practitioners. That is, we propose 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 propose 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 propose to modify the definition of ''group of physicians'' under § 414.1205 to also include the term ''group'' to reflect these proposals. We also propose to apply the VM beginning in CY 2017 to nonphysician eligible professionals who are solo practitioners. Additionally, we propose 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 propose 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.

We stated in the CY 2013 PFS final rule with comment period (77 FR 69307) that one of the principles that govern the implementation of the VM is our focus on shared accountability and that we have a role in fostering high value care for individual patients, but also focusing on how that patient interacts with the health care system generally. We stated our belief 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. We believe that our proposal to apply the VM to the physicians and nonphysician eligible professionals in a group will foster shared accountability among all of the eligible professionals in the group and encourage them to seek innovative ways to furnish high-quality, patient-centered, and efficient care to the Medicare FFS patients they treat.

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.[10] (77 FR 44996) 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 their ability and the resources to redesign such processes and workflows to achieve these objectives and furnish high-quality and cost-effective clinical care with greater care coordination.

As mentioned above, we are also proposing 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. The quality of care composite for these groups and solo practitioners would be based on the quality data submitted under the PQRS at the group or individual level in accordance with our 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 this proposed rule to calculate cost measures, we propose to calculate the cost composite using those cost measures. If a cost composite cannot be calculated for a group or solo practitioner, then we propose to classify the group or solo practitioner's cost composite as ''average'' as specified in § 414.1270. We seek comments on all of our proposed policies for applying the VM to nonphysician eligible professionals beginning in CY 2017.

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 propose to use a similar two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners. 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 propose 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 mechanism, as proposed in section III.K of this 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 this proposed rule. We also propose 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 this proposed rule. We note 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 this proposed rule. Lastly, we propose 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 this 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 section III.N.4.f of this proposed rule, for CY 2017, we are proposing to apply a −4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. We seek comment on these proposals.

For a group and a solo practitioner that would be 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) would need to be met during the reporting periods occurring in CY 2015 for the CY 2017 PQRS payment adjustment. As noted earlier, CY 2015 is the performance period for the CY 2017 payment adjustment period for the VM. In the event that the criteria that are finalized for the CY 2017 PQRS payment adjustment differ from what is proposed for the PQRS in this proposed rule, our intention is to align the criteria for inclusion in Category 1 to the extent possible with the criteria that are ultimately established for the CY 2017 PQRS payment adjustment.

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-

[10] 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.

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 propose to continue a similar phase-in of the quality-tiering based on the number of eligible professionals in the group. We propose 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 between 2 and 9 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, we propose that solo practitioners and groups with between 2 and 9 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 propose to revise § 414.1270 to reflect these proposals. We believe this proposed 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 seek comments on these proposals.

We believe it is appropriate to hold groups with between 2 and 9 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 note 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.

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 proposed rule, in the late summer of 2014, we plan to disseminate QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. These QRURs will 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. 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 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, 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, 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 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.

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 proposed rule, we are proposing to apply the VM to all physicians in groups with 2 or more eligible professionals and to solo practitioners who are physicians starting in CY 2017. In section III.N.4.b of this proposed rule, we discussed our proposal to also apply the VM starting in CY 2017 to all nonphysician eligible professionals in groups with 2 or more eligible professionals and to solo practitioners who are nonphysician eligible professionals. We describe in this section how we propose 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

Beginning with the CY 2017 payment adjustment period, we propose to apply the VM to physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners that participate in the Shared Savings Program. 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.

Beginning with the CY 2017 payment adjustment period, we propose 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). We propose 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 cost composite for groups and solo practitioners participating in the Shared Savings Program using the quality-tiering methodology would create two sets of standards for ACOs for their cost performance. We believe that having two sets of standards for ACOs for cost performance would be inappropriate and confusing. We seek comments on our proposals to classify the cost composite as ''average cost'' for groups and solo practitioners that participate in the Shared Savings Program during the payment adjustment period.

For groups and solo practitioners that 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 propose 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. We believe that it would be appropriate to apply the quality-tiering methodology to calculate the cost composite because these groups and solo practitioners are no longer part of the Shared Savings Program during the payment adjustment period and their cost benchmarks would be calculated only under the VM during the payment adjustment period.

Beginning with the CY 2017 payment adjustment period, we propose to calculate the quality of care composite score for the VM for groups and solo practitioners that participate in an ACO under the Shared Savings Program in accordance with the following policies:

(a) We propose 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 proposed rule, 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 propose 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 proposed rule, we are proposing 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 that participate in the Shared Savings Program during the payment adjustment period.

(b) For groups and solo practitioners that 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 propose 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. We believe 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.

(c) 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 propose to classify the quality of care composite for all groups and solo practitioners that participate in the ACO during the payment adjustment period as ''average quality'' for the payment adjustment period. We propose 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 believe this proposal is 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 note 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. However, we do not 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 believe 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 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 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 that participate in ACO 1.

(d) For groups and solo practitioners that 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 propose 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. However, we do not believe that 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 believe 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 are proposing to classify the quality of care composite for these groups and solo practitioners as ''average quality,'' we seek 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 seek comments on all of our proposals to calculate the quality composite for groups and solo practitioners participating in the Shared Savings Program as described above. A summary of these proposals is shown in Table 56 using TIN A and ACO 1 and ACO 2 as examples.

TABLE 56—SUMMARY OF PROPOSED POLICIES FOR GROUPS AND SOLO PRACTITIONERS WITH SHARED SAVINGS PROGRAM PARTICIPATION CHANGES

Scenario	TIN's Status during the performance period (for example, CY 2015)	TIN's Status during the payment adjustment period (for example, CY 2017)	TIN's Quality composite for the payment adjustment period (for example, CY 2017)	TIN's Cost composite for the payment adjustment period (for example, CY 2017)
a. *Continued ACO participation*—TIN A participates in ACO 1 during both the performance and payment adjustment periods.	TIN A is part of ACO 1.	TIN A is part of ACO 1.	Based on ACO 1's quality data from the performance period (for example, CY 2015.	Average cost.
b. Joining an existing ACO and not from another ACO—TIN A was not part of any ACO during the performance period, but participates in ACO 1 during the payment adjustment period (ACO 1 existed in the performance period) OR Joining an existing ACO from another ACO—TIN A participated in ACO 2 during the performance period, but is part of ACO 1 during the payment adjustment period (ACO 1 existed in the performance period)	TIN A is not part of any ACO and ACO 1 exists OR TIN A is not part of ACO 2 and ACO 1 exists	TIN A is part of ACO 1.	Based on ACO 1's quality data from the performance period (for example, CY 2015.	Average cost.
c. Joining a new ACO as a new TIN—TIN A participates in ACO 1 during the payment adjustment period (ACO 1 and TIN A did not exist in the performance period) OR Joining a new ACO and not from another ACO—TIN A was not part of any ACO during the performance period, but participates in ACO 1 during the payment adjustment period (ACO 1 did not exist in the performance period) OR Joining a new ACO from another ACO—TIN A participated in ACO 2 during the performance period, but is part of ACO 1 during the payment adjustment period (ACO 1 did not exist in the performance period).	TIN A and ACO 1 did not exist OR TIN A is not part of any ACO and ACO 1 did not exist OR TIN A is part of ACO 2 and ACO 1 did not exist.	TIN A is part of ACO 1.	Average quality	Average cost.
d. Dropping out of an ACO—TIN A participated in ACO 1 during the performance period, but is not part of any ACO during the payment adjustment period.	TIN A is part of ACO 1.	TIN A is not part of any ACO.	Average quality	Based on TIN A's cost data for the performance period using the quality-tiering methodology.

We believe that our proposal to apply the VM to groups and solo practitioners that participate in ACOs under the Shared Savings Program is appropriate in light of the statutory requirement under section 1848(p)(4)(B)(iii)(II) of the Act to apply the VM to all physicians and groups of physicians beginning not later than January 1, 2017. We believe our proposals, as described above, would further encourage groups and solo practitioners that participate in ACOs under the Shared Savings Program to furnish high quality care to Medicare beneficiaries by providing them with an opportunity to earn upward payment adjustments. We propose to apply the same VM, which would be calculated based on the policies proposed above, to all groups and solo practitioners, as identified by their TINs, that participate in an ACO under the Shared Savings Program during the payment adjustment period. Consequently, the same VM would also apply to the physicians and nonphysician eligible professionals in those groups and to the physicians and nonphysician eligible professionals who are solo practitioners that participate in the ACO during the payment adjustment period.

In section III.N.4.c of this proposed rule, we discussed our proposal to hold groups with between 2 and 9 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 propose to also hold harmless from any downward adjustments groups with between 2 and 9 eligible professionals and solo practitioners that 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, downward, or no payment adjustment in CY 2017, and groups with between 2 and 9 eligible professionals and solo practitioners would be subject to an upward or no payment adjustment in CY 2017. We also propose 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 propose to modify § 414.1210 to reflect these proposals.

(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.

In section III.N.4.a. of this proposed rule, we discussed our proposal to apply the VM to all physicians in groups with 2 or more eligible professionals and to solo practitioners who are physicians starting in CY 2017, as required under section 1848(p)(4)(B)(iii)(II) of the Act. In section III.N.4.b, we discussed our proposal to also apply the VM starting in CY 2017 to all nonphysician eligible professionals in groups with 2 or more eligible professionals and to solo practitioners who are nonphysician eligible professionals.

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. Beginning with the CY 2017 payment adjustment period, we propose to apply the VM to physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the relevant performance period in accordance with the policies described below.

(a) For groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period (for example, CY 2015) and do not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (for example, CY 2017), we propose to calculate the quality of care composite score for the VM for the payment adjustment period based on the following three scenarios:

Scenario 1: If a group participates in the PQRS as a group practice under the PQRS GPRO during the performance period and meets the criteria for satisfactory reporting of data on PQRS quality measures via one of the GPRO reporting mechanisms, as proposed in section III.K of this proposed rule, for the respective PQRS payment adjustment, then we propose to use the PQRS GPRO data to calculate the group's quality of care composite for the VM for the payment adjustment period. We propose to apply the same quality of care composite to all eligible professionals that bill under the group's TIN during the payment adjustment period. We also propose that if the group registers for GPRO for the performance period and does not meet the criteria for satisfactory reporting of data on PQRS quality measures via one of the GPRO reporting mechanisms for the respective PQRS payment adjustment, then the group would fall in Category 2. As discussed in section III.N.4.f of this proposed rule, for CY 2017, we are proposing to apply a −4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. In this case, all eligible professionals that bill under the group's TIN during the payment adjustment period would be subject to the −4.0% VM payment adjustment. We seek comment on this proposal.

Scenario 2: In the case of a group that does not report under the PQRS GPRO during the performance period and includes one or more eligible professionals that participate in a Pioneer ACO under the Pioneer ACO Model or in the CPC Initiative during the performance period, as well as other eligible professionals that do not participate in these models, we propose that if at least 50 percent of all eligible professionals in the group satisfactorily report quality data to CMS for the performance period, then we would calculate a quality of care composite using the quality-tiering methodology and the satisfactorily reported data on the PQRS quality measures submitted by the eligible professionals in the group as individuals under PQRS. For purposes of this scenario, by ''satisfactorily report quality data to CMS,'' we mean that 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 PQRS payment adjustment during the performance period, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the PQRS payment adjustment during the performance period, or successfully report quality data to the Pioneer ACO Model or the CPC Initiative during the performance period. The quality of care composite would be calculated using satisfactorily reported data on the PQRS quality measures submitted by the eligible professionals in the group as individuals under PQRS regardless of whether or not the eligible professionals who report the data participate in the Pioneer ACO Model or the CPC Initiative. We propose to assign the group a quality of care composite that is the higher of ''average quality'' or the group's actual classification as determined under the quality-tiering methodology. We propose to apply the same quality of care composite to all eligible professionals that bill under the group's TIN during the payment adjustment period, regardless of whether they participated in the model during the performance period.

We propose that if less than 50 percent of all eligible professionals in the group satisfactorily report quality data to CMS for the performance period, then this group would fall in Category 2. In other words, less than 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the PQRS payment adjustment during the performance period, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the PQRS payment adjustment during the performance period, or successfully report quality data to the Pioneer ACO Model or the CPC Initiative during the performance period. As discussed in section III.N.4.f of this proposed rule, for CY 2017, we are proposing to apply a −4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. In this case, all eligible professionals that bill under the group's TIN during the payment adjustment period would be subject to the −4.0 percent VM payment adjustment, regardless of whether they participated in the model during the performance period.

We note the eligible professionals in these groups that participate in the Pioneer ACO Model or the CPC Initiative submit quality data under their respective model. However, we do not believe that we can reasonably use the quality data submitted under these models in the calculation of the quality of care composite for these groups. At this time, we are unable to operationally integrate the data from these models with the value modifier program due to systems constraints and the unique nature of reporting for participants in these models. We also do not believe that we are able to predict how the quality data submitted under these models would affect the group's quality composite. We note that because these models are at the forefront of innovation, we believe that the eligible professionals participating in these models would have higher quality performance. For example, results from the first performance year of the Pioneer ACO Model demonstrated that Pioneer ACOs performed better than published rates in fee-for-service for 15 clinical quality measures for which comparable data are available. On readmissions, 25 of 32 Pioneer ACOs generated lower risk-adjusted readmission rates for their aligned beneficiaries than the benchmark rate for all Medicare fee-for-service beneficiaries. On clinical quality measures that assess hypertension control for Medicare beneficiaries, the median rate among Pioneer ACOs with diabetes was 68 percent compared to 55 percent as measured in adult diabetic population in 10 managed care plans across 7 states from 2000 to 2001. Also, on clinical quality measures that assess low density lipoprotein (LDL) control for patients with diabetes, the median rate among Pioneer ACOs for low density lipoprotein control among beneficiaries with diabetes was 57 percent compared to 48 percent in an adult diabetic population in 10 managed care plans across 7 states from 2000 to 2001. For these reasons, we seek to ensure that these groups are at least considered to have ''average'' quality, as reflected in our proposal above.

We also considered two alternatives to our proposal above for Scenario 2. First, we considered assigning these groups a quality composite of ''average quality'' without consideration of any PQRS quality data that may be available to calculate quality measure scores and a quality composite. We did not believe it would be appropriate to make such a proposal because we believe it is important to use data on quality, to the extent practicable, to determine a group's quality composite. Consequently, we believe it is appropriate to use the data that is reported under PQRS to calculate a quality composite for these groups. We recognize that some eligible professionals in these groups may not submit quality data under PQRS and that these professionals are likely to participate in a model and submit quality data through that model. Since we believe that participants in these models tend to perform better than average with regard to quality as described above, we believe that it is possible that we would underestimate a group's quality performance if we consider PQRS data only. Accordingly, to the extent that the data reported under PQRS by individual eligible professionals in the group results in a quality composite that is one standard deviation above average (that is, ''high quality''), we believe it is likely that this composite would increase by including data (were it available) from the eligible professionals who report quality data through the model. Therefore, we believe that it would be inappropriate to reduce a quality composite from ''high quality'' to ''average quality.'' Second, we considered assigning a quality composite of ''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 for the PQRS payment adjustment during the performance period, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the PQRS payment adjustment during the performance period, because we would not have quality data for more than half of the group that we could use to calculate a quality composite. Similarly, if at least 50 percent of all

eligible professionals in a group satisfactorily report or participate under PQRS as individuals, we considered using their PQRS quality data to calculate a quality composite for the group and applying the quality-tiering methodology to classify the group as high, average, or low quality. We did not believe it would be appropriate to make such a proposal. We do not believe that it is appropriate to classify a group as ''low quality'' when more than half of the eligible professionals in the group successfully report quality data (whether it be under PQRS or a model), even though we do not believe at this time we can reasonably use quality data reported through a model for the VM, because we believe that participants in these models would likely increase the group's quality performance were their data included. In other words, to the extent that the data reported under PQRS by individual eligible professionals in the group results in a quality composite that is ''low quality'' (that is, one standard deviation below average), we believe that this could be in part because the quality data of higher performing eligible professionals reported through the model would not be included in the calculation of the quality composite. Therefore, we believe it would be inappropriate to classify such a group as lower than ''average quality.''

We note that it may be possible for a group to have a disproportionately large number of eligible professionals participating in the Pioneer ACO Model or the CPC Initiative. In this instance, our proposal would result in the use of the PQRS data reported by a relatively small number of eligible professionals who are not participating in the model to determine the quality of care composite that would apply to all eligible professionals in the group. We seek comment on the degree to which this situation occurs and the appropriateness of our proposal in this instance, as well as alternatives to our proposal.

Scenario 3: If a group does not report under the PQRS GPRO during the performance period, consists entirely of eligible professionals that participate in the Pioneer ACO Model or the CPC Initiative, and successfully reports quality data to CMS under the model for the performance period, then we propose to classify the group's quality of care composite as ''average quality.'' We also propose to classify as ''average quality'' the quality of care composite of solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative and successfully report quality data to CMS under the model for the performance period. We propose to apply the same quality of care composite to all eligible professionals that bill under the group's TIN during the payment adjustment period. These eligible professionals submit quality data to the Pioneer ACO Model or the CPC Initiative; however, as discussed above, we do not believe that we can reasonably use the model quality data in the calculation of the quality of care composite for these groups and solo practitioners. Additionally, we propose that if the group or the solo practitioner does not successfully report quality data to CMS under the model for the performance period, then the group or solo practitioner would fall in Category 2. As discussed in section III.N.4.f of this proposed rule, for CY 2017, we are proposing to apply a −4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. In this case, all eligible professionals that bill under the group's TIN during the payment adjustment period would be subject to the −4.0% VM payment adjustment.

As an alternative to this proposal, we considered assigning ''average quality'' to groups and solo practitioners that do not successfully report quality data to CMS under the model for the performance period. We believe that this policy would not have been consistent with our proposal to consider groups and solo practitioners that do not satisfactorily report or participate for PQRS as Category 2 as described in section III.N.4.c of this proposed rule. We also believe that assigning ''average quality'' may inadvertently create incentives for groups and solo practitioners to not report quality data to CMS under these models.

For groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period (for example, CY 2015) and do not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (for example, CY 2017) (Scenarios 1 through 3 above), we propose to apply the quality-tiering methodology to calculate the cost composite for the VM for the payment adjustment period based on a group's and solo practitioner's performance on the cost measures, as identified under § 414.1235, during the performance period. We believe that it would be appropriate to apply the quality-tiering methodology to calculate the cost composite because these groups and solo practitioners are no longer part of the Pioneer ACO Model or the CPC during the payment adjustment period, and their cost benchmarks would be calculated only under the VM during the payment adjustment period.

(b) For groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period (for example, CY 2015) and participate in other similar Innovation Center models or CMS initiatives during the payment adjustment period (for example, CY 2017) (but not the Shared Savings Program), we propose to calculate the quality of care composite based on the three scenarios described above to the extent we are able. We recognize that these three scenarios might not be applicable to all of the various models and initiatives that may be developed in future years. We also propose to classify the cost composite for these groups and solo practitioners for the payment adjustment period as ''average cost.'' We believe that, for groups and solo practitioners participating in other similar models or initiatives during the payment adjustment period, calculating a cost composite based on the quality-tiering methodology may create two sets of standards for evaluating their cost performance; therefore, we believe it would be appropriate to assign ''average cost'' to these groups and solo practitioners. If we believe a different approach to applying the VM would be appropriate for a new model or initiative, we intend to address it in future rulemaking.

(c) For groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period (for example, CY 2015) and participate in an ACO under the Shared Savings Program during the payment adjustment period (for example, CY 2017), we propose to calculate the quality of care composite score based on the quality-tiering methodology using quality data submitted by the Shared Savings Program ACO from the performance period. For groups and solo practitioners that participate in a Shared Savings Program ACO during the payment adjustment period that did not exist during the performance period, we propose to classify the quality of care composite as ''average quality'' for the payment adjustment period because we would not have quality data from the performance period for that ACO. We also propose to classify the cost composite for the VM as ''average cost'' for groups and solo practitioners that participate in a Shared Savings Program ACO during the payment adjustment period. As we stated in section III.N.4.d.1 of this proposed rule, we believe that there are significant

differences in the methodology for calculating the cost benchmarks under the VM and the Shared Savings Program. Consequently, we believe that any attempt to calculate the cost composite for groups and solo practitioners participating in the Shared Savings Program using the quality-tiering methodology would create two sets of standards for ACOs for their cost performance, which would be inappropriate and confusing. These proposals are consistent with the proposals for participants in the Shared Savings Program described above.

(d) In section III.N.4.c of this proposed rule, we discussed our proposal to hold groups with between 2 and 9 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 propose to also hold harmless from any downward adjustments for CY 2017 groups with between 2 and 9 eligible professionals, where one or more eligible professionals participate in the Pioneer ACO Model or the CPC, and solo practitioners that 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 propose that groups where one or more eligible professionals participate in the Pioneer 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.

(e) In addition, beginning with the CY 2017 payment adjustment period, we propose to apply the VM to physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners that 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 propose 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 note 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 that participate. We are seeking 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.

As noted above, we recognize that the policies we finalize for the Pioneer ACO Model and the CPC Initiative after consideration of public comments 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 that we finalize after consideration of public comments, we propose to provide notice to participants in the model or initiative through the methods of communication that are typically used for the model or initiative.

We propose to modify § 414.1210 to reflect all of these proposals.

A summary of these proposals is shown in Table 57 using TIN A as an example.

TABLE 57—SUMMARY OF PROPOSED POLICIES FOR GROUPS AND SOLO PRACTITIONERS WITH PIONEER ACO MODEL, CPC INITIATIVE, OR OTHER SIMILAR INNOVATION CENTER MODEL OR CMS INITIATIVE PARTICIPATION CHANGES

Scenario	TIN's status during the performance period (for example, CY 2015)	TIN's status during the payment adjustment period (for example, CY 2017)	TIN's quality composite for the payment adjustment period (for example, CY 2017)	TIN's cost composite for the payment adjustment period (for example, CY 2017)
a. Scenario 1: TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period, but does not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (some or all of the eligible professionals in TIN A participate in the Pioneer ACO Model or CPC Initiative) AND TIN A registers for PQRS GPRO for the performance period	TIN A is part of the Pioneer ACO Model or CPC Initiative.	TIN A is not part of the Shared Savings Program or other similar Innovation Center models or CMS initiatives.	If TIN A satisfactorily reports under PQRS GPRO for the performance period: Based on TIN A's PQRS GPRO data. If TIN A does not satisfactorily report under PQRS GPRO for the performance period: TIN A falls in Category 2 and a −4.0 percent VM is applied to the TIN in the payment adjustment period.	If TIN A satisfactorily reports under PQRS GPRO for the performance period: Based on TIN A's cost data for the performance period using the quality-tiering methodology.

TABLE 57—SUMMARY OF PROPOSED POLICIES FOR GROUPS AND SOLO PRACTITIONERS WITH PIONEER ACO MODEL, CPC INITIATIVE, OR OTHER SIMILAR INNOVATION CENTER MODEL OR CMS INITIATIVE PARTICIPATION CHANGES—Continued

Scenario	TIN's status during the performance period (for example, CY 2015)	TIN's status during the payment adjustment period (for example, CY 2017)	TIN's quality composite for the payment adjustment period (for example, CY 2017)	TIN's cost composite for the payment adjustment period (for example, CY 2017)
a. Scenario 2: TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period, but does not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (TIN A has one or more eligible professionals that participate in the Pioneer ACO Model or CPC Initiative and other non-participating eligible professionals) AND For the performance period: TIN A does not report under PQRS GPRO; some eligible professionals report quality data to the Pioneer ACO Model or the CPC Initiative and others report under PQRS as individuals.	TIN A is part of the Pioneer ACO Model or CPC Initiative.	TIN A is not part of the Shared Savings Program or other similar Innovation Center models or CMS initiatives.	If at least 50 percent of all eligible professionals in TIN A satisfactorily report quality data to CMS for the performance period: Higher of ''average quality'' or the actual classification under the quality-tiering methodology based on PQRS quality data submitted by the eligible professionals as individuals. If less than 50 percent of all eligible professionals in TIN A satisfactorily report quality data to CMS for the performance period: TIN A falls in Category 2 and a −4.0 percent VM is applied to the TIN in the payment adjustment period.	If at least 50 percent of all eligible professionals in TIN A satisfactorily report quality data to CMS for the performance period: Based on TIN A's cost data for the performance period using the quality-tiering methodology
a. Scenario 3: TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period, but does not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (all eligible professionals in TIN A participate in the Pioneer ACO Model or CPC Initiative) AND For the performance period: TIN A does not report under PQRS GPRO; TIN A reports quality data to the Pioneer ACO Model or the CPC Initiative.	TIN A is part of the Pioneer ACO Model or CPC Initiative.	TIN A is not part of the Shared Savings Program or other similar Innovation Center models or CMS initiatives.	If TIN A successfully reports quality data to the Pioneer ACO Model or CPC Initiative for the performance period: Average quality. If TIN A does not successfully report quality data to the Pioneer ACO Model or CPC Initiative for the performance period: TIN A falls in Category 2 and a −4.0 percent VM is applied to the TIN in the payment adjustment period.	If TIN A successfully reports quality data to the Pioneer ACO Model or CPC Initiative for the performance period: Based on TIN A's cost data for the performance period using the quality-tiering methodology.
b. TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period and participates in other similar Innovation Center models or CMS initiatives during the payment adjustment period (but not the Shared Savings Program).	TIN A is part of the Pioneer ACO Model or CPC Initiative.	TIN A is part of other similar Innovation Center models or CMS initiatives (but not the Shared Savings Program).	Based on Scenarios 1–3	Average cost.
c. TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period and participates in an ACO under the Shared Savings Program during the payment adjustment period.	TIN A is part of the Pioneer ACO Model or CPC Initiative.	TIN A is part of an ACO under the Shared Savings Program.	Based on the Shared Savings Program ACO's quality data for the performance period. If the ACO did not exist in the performance period: Average quality.	Average cost.

e. Clarification Regarding Treatment of Non-Assigned Claims for Non-Participating Physicians

As indicated earlier, section 1848(p) of the Act requires the Secretary to establish a payment modifier that provides for differential payment to a physician or a group of physicians under the PFS based upon the quality of care furnished compared to cost during a performance period. 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 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 are proposing to clarify that we would apply the VM only to assigned services and not to non-assigned services starting in CY 2015. 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 invite comments on this proposed clarification.

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.

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 (77 FR 69324).

We received comments on the CY 2014 proposed rule suggesting that the payment adjustment under the VM must be of significant weight to drive physician behavior toward achieving high quality and low cost care and that the VM should represent a larger percentage of physician payments under the PFS that should be increased incrementally from 2.0 percent and subject to annual review. In our response to these comments, we agreed that the amount of payment at risk should be higher to incentivize physicians to provide high quality and low cost care. We also stated that our experience under PQRS has shown us that a 1.0 or 2.0 percent incentive payment has not produced widespread participation in the PQRS. Thus, we believed that we needed to increase the amount of payment at risk for the CY 2016 VM to incentivize physicians and groups of physicians to report PQRS data, which will be used to calculate the VM. We continue to believe this is the appropriate strategy.

We believe that we can increase the amount of payment at risk because we can reliably apply a VM to groups with 2 or more eligible professionals and to solo practitioners in CY 2017 as discussed in section III.N.4.a. of this proposed rule. Therefore, we propose 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. That is, for CY 2017, we propose 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 propose 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 proposed rule, we are proposing to hold solo practitioners and groups with between 2 and 9 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. Based on an estimate of these funds, we also propose to increase the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0× for groups and solo practitioners classified as high quality/low cost and to set the adjustment to +2.0× for groups and solo practitioners classified as either average quality/low cost or high quality/average cost. We also propose to continue to provide an additional upward payment adjustment of +1.0× 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 propose to revise § 414.1270 and § 414.1275(c) and (d) to reflect the proposed changes to the payment adjustments under the VM for the CY 2017 payment adjustment period. Table 58 shows the proposed quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance). We believe that the proposed VM amount differentiates between cost and quality tiers in a more meaningful way. We seek comments on all of these proposals.

TABLE 58—CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+2.0×*	+4.0×*
Average Cost	−2.0%	+0.0%	+2.0x*
High Cost	−4.0%	−2.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0× if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

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 Table 58) would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

In section III.N.4.d of this proposed rule, we discussed our proposal to apply the VM to physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to physicians and nonphysician eligible professionals 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 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). We note that this final list may not be available until after the beginning of the payment adjustment period. Therefore, we propose to calculate preliminary payment adjustment factors (''x'' in Table 58) 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 proposed rule.

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: We believe 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 propose to include 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 are described in Tables 21 through 49 of this proposed rule.

PQRS Quality Measures: We propose 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 are described in Tables 21 through 49 of this proposed rule. We propose that groups with 2 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. We propose 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 propose 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 propose 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. 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.

While 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 note 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 of a measure's performance rate during the year prior to the performance period. In the CY 2013 PFS final rule with comment period (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 hence, performance on that measure will not be included in the quality composite. Therefore, we propose to apply that policy to 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). Performance on these measures would not be included in the quality composite for the VM because we would not be able to calculate benchmarks for them. This proposal 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 welcome public comment on this proposal.

In addition, we note that the PQRS administrative claims option, which included the outcome measures described in § 414.1230, is no longer available through PQRS. We propose 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). We welcome public comment on this proposal.

Quality Measures for the Shared Savings Program: Starting with the CY 2017 payment adjustment period, as described in section III.M. of this proposed rule, we are proposing to apply the value modifier to groups and solo practitioners participating in ACOs under the Shared Savings Program. To do so, we are proposing quality measures and benchmarks for use with these groups and solo practitioners and seek public comment on these proposals. We describe these proposals more fully below.

With regard to quality measures, we note 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 that participate in an ACO under the Shared Savings Program, we propose to use the quality measures that are identical for the two programs. Specifically, for the CY 2017 payment adjustment period, we propose 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 that participate in an ACO under the Shared Savings Program. Because the ACO GPRO measures and PQRS GPRO Web Interface measures will be the same in CY 2015, we propose 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. Utilizing these GPRO Web Interface measures in this regard further encourages successful quality reporting for Shared Savings Program ACOs. Additionally, we believe 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 propose 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. 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 do not propose to include these measures for groups and solo practitioners that participate in ACOs under that program. We propose to modify the regulations at § 412.1230 accordingly.

To determine the standardized scores for these quality measures proposed for use with those participating in ACOs under the Shared Savings Program, we propose 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. In other words, we believe that use of the VM benchmarks creates a fair comparison among groups and solo practitioners because we believe 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 the VM benchmarks are appropriate because they include all PQRS data available (77 FR 69322), including quality data used for the Shared Savings Program. On the other hand, while the Shared Savings Program develops benchmarks using all available Medicare fee-for-service data, we do not believe it is appropriate to use the 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 are calculated using a different methodology, providing gradients by decile (including the median) of national performance based on data two years prior to the performance period (78 FR 74759 through 74760).

All-Cause Hospital Readmissions Measure: In addition, since finalizing the all-cause hospital readmissions measure described at § 414.1230(c) in the CY 2013 PFS final rule with comment (77 FR 69285), we have investigated the reliability of this measure. According to § 414.1265, to calculate a composite score for a quality or cost measure based on claims, a group subject to the VM must have 20 or more cases for that measure. 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. Nonetheless, the finding that the average reliability exceeded 0.4 for groups with 200 or more cases included all group sizes (1 or more eligible professionals).

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 propose to change the reliability policy (minimum number of cases) with respect to this measure. Specifically, beginning with the CY 2017 payment adjustment period, we propose 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 propose 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 note that we would only apply it to the all-cause hospital readmissions measure as it is calculated for groups or solo practitioners that are not part of a Shared Savings Program ACO. In instances where we are including Shared Savings Program data for groups or solo practitioners that 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. We believe that 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 that have 200 or more cases. We propose to modify the regulations at § 414.1265 to reflect this proposal. We welcome comments on this proposal.

If we were to revise the minimum case size for the all-cause hospital readmissions measure for the quality composite of the VM, we note that 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.

i. Proposed 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 believe 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 are proposing 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. Specifically, under this initial corrections process, for the CY 2015 payment adjustment period, we are proposing 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 seek 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 propose 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 propose to recompute a TIN's cost composite in the event we determine that we have made an error in its calculation. We propose 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 note 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 are proposing 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 are proposing 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 will 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 as described above under section III.K. for the CY 2016 payment adjustment period, we propose 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 note that if the operational infrastructure is not available to allow this recomputation, we propose 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 propose 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 note 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.

In future rulemaking and guidance, we plan to address how we would propose to refine and further develop this expanded informal inquiry process to allow for corrections for the value modifier. We believe it is important that the corrections process not undermine incentives for appropriate timely reporting. We welcome comment on these proposals, especially regarding the types of errors, timeline and other considerations that should be given to both the initial corrections process in the CY 2015 payment adjustment period and the corrections process we propose beginning with the CY 2016 payment adjustment period.

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).

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the MSPB measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. 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 are proposing to address two of the major concerns that Committee raised in its review of the measure. First, we propose modifications to our two-step attribution methodology. Second, we propose to reverse the current exclusion of certain Medicare beneficiaries during the performance period. We discuss these proposals further below, and they would apply beginning with the CY 2017 payment adjustment period for the VM. The proposals would apply to all five of the total per capita cost measures under § 414.1235(a)(1) through (5). 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 5 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 propose 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 agree 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 propose to move these NPs, PAs, and CNSs from Step 2 of the attribution method to Step 1. This proposed 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 propose 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 propose 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 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 proposed 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 proposed 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 propose these modifications only for groups and solo practitioners who are not participating in the Shared Savings Program. We note 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.

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 note that for the purposes of the VM, we intend 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 welcome 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 (5) and to the claims-based quality measures under § 414.1230 of the VM.

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 agree that it is important to include certain beneficiaries with these costs during the performance period. As a result, we propose to include certain part-year Medicare FFS beneficiaries. This proposed change would affect all five of

the total per capita cost measures under § 414.1235(a)(1) through (5). We believe the proposed change would provide a more complete assessment of end of life costs associated with the patients a physician group sees during the year. We seek comment on this proposal.

We propose 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). 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 propose 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, while we believe inclusion of new enrollees is inconsistent with GPRO's methodology, it would be consistent with the Shared Savings Program's methodology. We welcome comments on the inclusion of these part-year beneficiaries. We also welcome 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.

In this proposed rule, we are choosing not to address the other concerns about the total per capita cost measures that were raised by NQF. First, we are deferring 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 are not proposing to include Part D data in the total per capita cost measures at this time due to the complexity of the issue. Based on data compiled by the Medicare Payment Advisory Commission (MedPAC), we estimate that approximately 60 percent of Medicare FFS beneficiaries were enrolled in stand-alone Part D in 2013.[11] Including Part D data would incorrectly indicate higher costs for these beneficiaries compared to others without Part D coverage. Before we are able to propose inclusion of Part D data, we would need to determine an approach to address this issue. We welcome comments on suggested methods for including Part D data in the total per capita cost measures.

k. Discussion Regarding Treatment of Hospital-Based Physicians

We are considering 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 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 are considering 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 note 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 register for PQRS reporting. In other words, 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.

To identify groups or solo practitioners that would have Hospital VBP Program performance data in their VM or allow such groups to elect its inclusion, we first have to identify who would have this option. Because the VM is applied at the TIN level, we believe that the election to include Hospital VBP Program data must also be made at the TIN level. We considered two general methods for identifying which TINs represent hospital-based physicians and should therefore have Hospital VBP Program data included or have the option to elect its inclusion. The first approach would be self-nomination, by which a group would attest that it is comprised primarily of hospital-based physicians. This approach would be consistent with public comment we received on the CY 2013 PFS proposed rule (77 FR 69312), in which commenters suggested that we should include hospital performance information on a voluntary basis and that it should be based on self-nomination. The second approach would be for CMS to specify criteria that a TIN would have to satisfy, to have Hospital VBP Program data included or have the option to elect its inclusion. The latter approach might provide a more objective method for determining whether a TIN would be eligible to elect inclusion of hospital performance information or would have it automatically included in its VM. These criteria could include specialty types or percentage of Medicare payments for services provided in the hospital setting. For example, the EHR Incentive Program has defined in 42 CFR 495.4 a hospital-based EP generally as an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting. We could adopt a similar criterion for identifying hospital-based physicians for the purpose of electing or receiving mandatory inclusion of Hospital VBP Program data in the VM. If we were to take the approach of identifying appropriate criteria for eligibility for inclusion of hospital performance data, we would need to then determine whether the criteria

[11] 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).

would have to apply to the majority of physicians within a given TIN, or whether the TIN as a whole would have to meet the criteria in the aggregate. That is, using the example criterion above, we could either require that 90 percent of the total Medicare covered professional services provided by all physicians within a given TIN are furnished in a hospital setting or require that some proportion of the individual physicians within a TIN provide 90 percent of their individual Medicare covered services in the hospital setting. Additionally, since we are proposing to expand application of the VM to nonphysician eligible professionals, we seek comment on whether these methods should apply in identifying hospital-based nonphysician eligible professionals in addition to hospital based physicians. We welcome 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.

After determining which groups or solo practitioners would be eligible to have hospital VBP Program performance data included or to elect inclusion of hospital VBP Program performance data in the VM, we would require a methodology to determine which hospital or hospitals' performance would apply to a given TIN. We could base this determination on the plurality of services provided by a TIN. That is, the TIN would be attributed the Hospital VBP Program performance of the hospital at which its physicians (or physicians and nonphysician eligible professionals) billed the most professional services during a given performance period. Alternatively, we could attribute hospital performance to a TIN that provided some threshold of its hospital-based services at that hospital. For example, we could require that a TIN have performed at least 30 percent of its hospital-based services at a given hospital to have that hospital's performance included in the TIN's VM. In that example, a TIN could have up to three hospitals' performance included in its VM. We could weight the performance of the hospitals included, based on Medicare dollars paid to the TIN for services their physicians (or physicians and nonphysician eligible professionals) provided to beneficiaries hospitalized at a given hospital, or based on number of cases treated by physicians (or physicians and nonphysician eligible professionals) from the TIN that are discharged from a given hospital. We welcome public comment on these or other alternatives 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 is included.

After we have determined which hospital or hospitals' Hospital VBP Program performance data would be included in a TIN's VM, we would have to incorporate that hospital's or hospitals' Total Performance Score(s) (TPS(s)) or some subset of it into the VM. Under the Hospital VBP Program, a hospital receives a TPS, which is a weighted total of underlying quality performance scores the hospital receives on quality and efficiency measures included in the program. Further details about the Hospital VBP Program may be found on CMS' Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/.* We generally finalize the measures, domains into which the measures are grouped for scoring purposes, and scoring methodology (which includes the measure and domain weights that apply to a particular program year) for each Hospital VBP Program year in the IPPS/LTCH final rule that we issue each summer. For the FY 2017 Hospital VBP Program, the finalized domains are: Safety; Clinical Care (subdivided into Clinical Care—Outcomes and Clinical Care—Process); Efficiency and Cost Reduction; and Patient and Caregiver Centered Experience of Care/Care Coordination (78 FR 50703 through 50704). Other proposals for the FY 2017 Hospital VBP Program can generally be found in the FY 2015 IPPS/LTCH Proposed Rule (79 FR 28117 through 28134).

When determining what part of the TPS to include in the VM, we have to consider the varied performance periods of measures included in the Hospital VBP Program. The majority of measures used in the Hospital VBP Program are scored based on calendar year performance periods, and performance on measures under the program is used to adjust the base-operating DRG payment made to hospitals under the IPPS on a fiscal year basis. For these measures in which calendar year performance periods are used, hospitals generally report data two calendar years prior to the fiscal year in which their performance on those measures will affect their payment. For example, hospitals' CY 2016 performance on these measures under the program would affect their FY 2018 payments. If we were to incorporate Hospital VBP Program performance into the VM as in the example, we could incorporate the CY 2016 performance into VMs for CY 2018 physician payments.

In determining which portion of the TPS to include in the VM, we also have to consider the incentives generated by different approaches. Inclusion of the entire TPS score encourages shared accountability for and shared incentive to improve on all aspects of the quality of care provided during a hospitalization, while selecting some subset might better target factors over which physicians exert more influence. The latter approach might, for example, exclude measures such as HCAHPS survey dimensions focused on nursing interventions.

We considered three options for including Hospital VBP Program performance in the VM: (1) Include the entire TPS in the cost composite; (2) Include the Efficiency and Cost Reduction domain score in the cost composite, and include all or some subset of the other domain scores in the quality composite; and (3) Include some subset of the measures in the cost and quality composites. The first approach, inclusion of the TPS in the cost composite, was suggested during public comment on the CY 2014 PFS rule (78 FR 74775). This approach is a straightforward one and it encourages joint accountability and coordination between hospitals and physicians on all aspects of hospital quality. However, it could be construed as counting quality measures within the cost composite because, as noted above, the TPS is computed based on hospital performance on measures in a number of quality domains in addition to hospital performance on the Medicare Spending Per Beneficiary measure in the Efficiency and Cost Reduction domain. Additionally, we note that the VM is structured in such a manner that a score would need to be included as part of either the quality composite or the cost composite. Under this approach and the second one, measures with performance periods exceeding one calendar year would be captured in the VM for a given payment year. The second approach, inclusion of the Efficiency and Cost Reduction domain score in the cost composite and all or some subset the other domain scores in the quality composite remains relatively straightforward, encourages shared accountability and coordination between hospitals and physicians on all aspects of hospital quality, and enables us to avoid counting quality measures

within the VM cost composite, but it could still capture measures with performance periods exceeding a calendar year in the VM for a given year. We note that for the Hospital VBP Program, the Efficiency and Cost Reduction domain includes Medicare Spending per Beneficiary measure attributed to hospitals and that, starting with the CY 2016 payment adjustment period, the VM includes as part of its total cost domain the Medicare Spending per Beneficiary measure attributed to groups. While the third approach would be the most complex one, inclusion of some subset of the domain measures in the cost and quality composites would enable us to use only measures with performance periods aligning with the remainder of the VM measures to be included in the quality and cost composites, if we wished to do so. It would also enable us to identify measures over which we believe hospital-based physicians exert sufficient influence to be held accountable through payment adjustments. The third approach places less emphasis on hospital and physician coordination to improve all aspects of the quality of care provided during a hospitalization and it requires a judgment call regarding which measures to include. We believe that the second approach, inclusion of all TPS domains or some subset of the TPS domains in the VM, with the Efficiency and Cost Reduction domain included in the cost composite and the other domains (based on whether all of the measures in the domain have the same performance periods as the performance period being considered in the VM) included in the quality composite would strike the best balance between a straightforward approach, appropriate capture of different aspects of the TPS as they relate to the VM composites, and encouraging physician and hospital coordination to improve all aspects of care provided to Medicare beneficiaries who are hospitalized. We welcome 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. We also welcome 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.

Once we have determined which portion of the TPS to include in the VM, if we were to move forward with including Hospital VBP performance data into the VM, we would need to determine how we would incorporate it into the quality and cost composite scores. If more than one hospital's Hospital VBP Program performance data were to be included in a given TIN's VM because a multiple hospital attribution approach were selected, as discussed above, we would first weight the hospitals' performance. That performance could be measured at the TPS level, the domain level, or the individual measure level, depending which we decide to use, also discussed above. We could treat the TPS itself, the individual domain, or the individual measure as an additional measure in the composite or composites into which we incorporate it. Under this approach, the TPS, domain, or measure score could be given a standardized score, similar to other measures within the VM. For example, a given hospital's Efficiency and Cost Reduction Domain score would be arrayed along with that of all other TINs electing inclusion and the standardized score would be calculated, according to the methodology we finalized in the CY 2013 PFS final rule with comment period (77 FR 69321). That standardized score would then be weighted into the cost composite for the value modifier. The weight could depend on the number of measures underlying the domain score or TPS, it could be weighted evenly with other composite measures if calculated at the individual measure level, or it could be assigned a weight based on relative importance of the measure, to be determined through rulemaking. We welcome public comment on this potential methodology or other approaches for including Hospital VBP Program performance into a TIN's VM.

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. In the fall of 2013, we provided QRURs to certain physicians and groups as discussed below, which were based on CY 2012 data. We intend to make reports based on CY 2013 data available in the fall of 2014. These reports provide physicians and groups of physicians with comparative performance data (both quality and resource use) that can be used to improve quality and coordinate care furnished to Medicare FFS beneficiaries. Additionally, in June 2013 and June 2014, we provided Supplemental QRURs to group report recipients that featured episode-based costs of care. We derived these episode-based costs using an episode grouper as required by section 1848(n)(9)(A) of the Act, as well as using methodologies proposed in the FY 2015 IPPS rule to measure episode costs under the Hospital Value Based Purchasing program (79 FR 28122 through 28124).

a. CY 2013 Quality and Resource Use Reports Based on CY 2013 Data and Disseminated in CY 2014

On September 16, 2013, we made available CY 2012 QRURs to 6,779 groups nationwide with 25 or more EPs. These reports covered approximately 400,000 physicians practicing in large medical groups. The QRURs provided groups of 100 or more EPs with quality-tiering information on 2012 data that they could use to decide whether to elect to be assessed under the quality-tiering approach that we adopted for the VM that will be applied in 2015, based on 2013 performance. Additionally, and in response to feedback we received from prior year recipients of the QRURs, the CY 2012 QRURs contained detailed beneficiary-specific data on each group's attributed beneficiaries and their hospitalizations, and the group's associated eligible professionals. Complementing the CY 2012 QRURs were three downloadable drill down tables that provide information on each beneficiary attributed to the group and each eligible professional billing under the group's TIN. We have received very positive feedback from report recipients and expect to enhance the information we provide in future years.

In the late summer of 2014, we plan to disseminate 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. Additionally, in CY 2015, the VM will not apply to any group that participated in the Shared Saving Program, the Pioneer ACO model, or the Comprehensive Primary Care Initiative during the performance period (CY 2013). These reports will 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.

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 have 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 June 2013, we made available to 54 large group practices Supplemental QRURs based on 2011 data that illustrated the general approach to classifying episodes of care. The 2011 Supplemental QRURs included episode-based costs for five clinical conditions (pneumonia, acute myocardial infarction (AMI), coronary artery disease, percutaneous coronary intervention (PCI), and coronary artery bypass graft (CABG)), which also were broken into 12 episode subtypes to account for various underlying clinical factors. We chose these episode types to gain experience with the prototype methodology of the episode grouper in acute, chronic, and procedural conditions. In summer 2014, we distributed Supplemental QRURs based on 2012 data to a greater number of groups (groups with at least 100 EPs [12] 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). These 6 additional episode-based measures will be described following discussion of the 20 episode subtypes.

For the 20 episode subtypes discussed above, we applied different attribution rules, depending on episode type (for example, chronic, acute, or procedural) and whether the episode included a hospitalization. Following feedback we received from physician groups on the 2011 Supplemental QRURs, we have simplified our attribution rules to a single plurality attribution rule with a 20 percent minimum threshold. We believe that it is critical to attribute an episode to the group of physicians that is in the best position to oversee the quality of care furnished and the resources used to furnish that care. For chronic episodes, attribution was based on the plurality of outpatient E&M visits during the episode, because these conditions seem best managed in an outpatient setting. For acute inpatient-based episodes, attribution was based the plurality of inpatient E&M visits during the trigger event; for outpatient-based acute episodes, attribution was based on the plurality of E&M visits during the entire episode. For procedural episodes, attribution is made to the group that includes the performing surgeon. For chronic and acute episodes, attribution required at least 20 percent of the relevant type of E&M visits, as applicable to the episode type. Additional tie-breaking rules were applied when necessary, and 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.*

To control for patient case-mix, we applied a risk-adjustment methodology. We also used a slightly different risk adjustment methodology to adjust the costs for the underlying risk factors for the beneficiaries with these episodes as compared to the total per capita cost measures that we have used in the CY 2013 QRURs. The episode grouper used to generate the 2012 episode data for the 20 episode subtypes, as discussed above, adjusted costs for health and treatment history in the 6 months prior to the beginning of the episode. The risk-adjustment methodology calculated each episode's expected cost based on health (for example, severity), and non-health (for example, age) explanatory variables. Using these variables, the risk-adjustment model calculated the predicted cost of an episode using information available at the start of the episode. The use of such a prospective risk model avoids allowing providers to influence their risk-adjusted costs by changing their treatment patterns during the episode. We are continuing to examine ways to refine this approach as we develop further episode costs for additional clinical conditions. All cost figures used in the risk-adjustment model are payment-standardized.

We have worked with stakeholders and specialty societies to gain input for the next iteration of the Supplemental QRURs. Based on input received, we have modified episode attribution rules, and increased drill down capability. The Supplemental QRURs contained summary information about each episode type, comparisons to national benchmarks, as well as specific information describing each episode attributed to the group of physicians. We view these 2012 Supplemental QRURs as part of an extended process of incorporating episode costs into the QRURs. We intend to further develop the episode grouper and to broaden the range of conditions that are addressed by episode grouping, such as the additional clinical episode based measures we adapted from the Hospital Value-Based Purchasing Program. The feedback that CMS expects from the medical practice groups on the 2012 Supplemental QRURs will inform next steps.

In the future, we plan to further develop these episode reports and to include not only additional episodes, and to make this information available to an even greater number of medical group practices. In addition, we have begun preliminary investigation of how to marry these measures of resource use with clinical quality measures included in the PQRS, because resource use is to be considered in context of the quality of care furnished for the value modifier. We have also begun investigation of how to align episode measures across provider settings and describe this effort more below.

We note that for the 2012 Supplemental QRURs released in summer of 2014, we included six additional clinical episode-based measures that were adapted from measures proposed for future inclusion in the Hospital VBP Program. In the FY 2015 IPPS proposed rule (79 FR 28122 through 28124), we discussed six clinical episode-based condition-specific measures for hospitals that we also adapted for use in the 2012 Supplemental QRURs. In that proposed rule, we stated that these measures that we are considering for potential future inclusion in the Hospital VBP Program would create additional incentives for coordination between hospitals and physicians to optimize the care they provide to Medicare beneficiaries and would facilitate alignment between the Hospital VBP Program and the VM. Initially, these measures have been included only in the Physician

[12] 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).

Feedback Program, through the 2012 Supplemental QRURs, and we would consider whether to propose their inclusion in the VM through future rulemaking.

The episode-based measures we included in the 2012 Supplemental QRURs and are considering for future inclusion in the Hospital VBP Program are similar in many ways to the MSPB measures already included in the Efficiency domain of the Hospital VBP Program and finalized in the CY 2014 PFS final rule (78 FR 74780) for the VM. As discussed in the FY 2015 IPPS proposed rule (79 FR 28123), like the MSPB measure, these episode-based standardized payment measures would include services initiated during an episode that spans from 3 days prior to a hospital admission through 30 days post-discharge from the hospital. While the MSPB measure includes all Medicare Part A and Part B payments during this time window, the six hospital-based episodes only include Medicare payments for services that are clinically related to the health conditions treated during the hospital stay that triggered the episode. We sum the standardized Medicare payment amounts for Part A and Part B services provided during this timeframe. Medicare payments included in these episode-based measures are standardized according to the CMS standardization methodology finalized for the MSPB in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626). Episodes in the six new measures are risk-adjusted in a manner similar to the MSPB measure risk adjustment methodology finalized in the FY 2013 IPPS final rule (76 FR 51625 through 51626).[13] The payment standardization methodology is available in the document entitled ''CMS Price Standardization'' available at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.* The risk adjustment methodology specific to these six episode-based standardized payment measures can be found on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html.* Risk adjustment and payment standardization allow us to compare performance on these measures in the QRURs, attributed to a physician group, across physician groups.

We included three medical and three surgical episodes in the 2012 Supplemental QRURs. The medical episode measures are for the following conditions: (1) Kidney/urinary tract infection; (2) cellulitis; and (3) gastrointestinal hemorrhage. A medical episode is 'triggered' by an inpatient claim with a specified MS–DRG. The surgical episode measures are: (1) Hip replacement; (2) knee replacement/revision; and (3) lumbar spine fusion/refusion. A surgical episode is triggered when an inpatient claim has one of the specified MS–DRGs and at least one of the procedure codes specified for that episode. We welcome public comment 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 the 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.*

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 welcome public comments on these specifications and the construction of the six clinical episode-based measures that we included in the 2012 Supplemental QRURs.

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 are considering 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 welcome public comments on the specifications included on the Web site and the construction of the episode-based payment measures that we are considering.

c. Future Plans for the Physician Feedback Reports

We will continue to develop and refine the annual QRURs in an iterative manner. As we have done in previous years, we will seek to further improve the reports by welcoming suggestions from recipients, specialty societies, professional associations, and others. We have worked with several specialty societies to develop episode costs or other cost or utilization metrics to include in the annual QRURs. We believe these efforts could be productive as we use the QRURs to not only describe how the VM would apply, but in addition to provide groups with utilization and other statistics that can be used for quality improvement and care coordination.

In the late summer of 2014, we plan to disseminate 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. Additionally, the VM will not

[13] There are a few difference between the risk adjustment approaches for the six clinical episode-based measures and the MSPB. MSPB episodes are risk-adjusted at the Major Diagnostic Category (MDC) level, whereas two of the new episode-based measures, the hip episode measure and the knee episode measure, represent conditions that are in the same MDC. Accordingly, the six clinical episode-based measures are individually risk-adjusted at the specific episode type level, to recognize the distinctions.

apply to any group that participated in the Shared Saving Program, the Pioneer ACO model, or the Comprehensive Primary Care Initiative during the performance period (CY 2013). These reports will 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. Improvements to this year's reports include: Additional supplementary information on the specialty adjusted benchmarks; inclusion of the individual PQRS measures for informational purposes for individual EPs reporting PQRS measures on their own; enhanced drill down tables; and a dashboard with key performance measures. The reports will be based on the VM policies that were finalized in the CY 2013 PFS final rule with comment period (77 FR 69310), and that will affect physician payment starting January 1, 2015. Groups will, therefore, have an opportunity to see how the policies adopted will apply to them. After the reports are released 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.

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.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The salary estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the June 2012 Employer Costs for Employee Compensation report by the Bureau.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). For cohesion, the ICRs are set out below under the same headings found in sections II (Provisions of the Proposed Rule for PFS) and III (Other Provisions of the Proposed Regulations) of this preamble.

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 would remove the requirement that nonphysician RHC or FQHC practitioners be W–2 employees. This action would 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

While this provision concerns the evaluation of 3021-funded models, section 3021(a) of the Affordable Care Act exempts any collection of information associated with the testing and evaluation or expansion of 3021-funded models from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

3. ICRs Regarding Molecular Diagnostic Testing Local Coverage Determination Process

The information collection requirements and burden associated with the proposed LCD process for clinical diagnostic laboratory testing would 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.*).

4. ICRs Regarding the Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

In this section of this preamble, we are soliciting public comments regarding substitute physician billing arrangements. Since we are not proposing any new or revised collection of information requirements, this section is not subject to the requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

5. Reports of Payments or Other Transfers of Value to Covered Recipients ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904(c)(8)(d)(3), and (g))

The proposed amendment of § 403.904(c)(8) would require applicable manufacturers and applicable group purchasing organizations (GPOs) to report the marketed name of covered and non-covered drugs, devices, biologicals and medical supplies. This amendment would have 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 either the marketed name, therapeutic area, or product category for devices and medical supplies. This requirement has been approved by OMB under control number 0938–1173.

Section 403.904(d)(3) would require that applicable manufacturers and applicable GPOs 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 would take each applicable manufacturer and applicable GPO to revise their reporting system to report the form of payment.

The proposed removal of § 403.904(g) would require applicable manufacturers and applicable GPOs of covered drugs, devices, biologicals, and medical supplies to 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 would 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 would 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 $47.55/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 OCN 0938–1173.

6. ICRs Regarding Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

The annual burden estimate is calculated separately for the 2015 PQRS for: (1) Individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR, (3) EHR-based reporting mechanisms, and (4) group practices using the group practice reporting option (GPRO). There is also a separate annual burden estimate for qualified registry and QCDR vendors who wish to be qualified to submit quality measures data. 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.'' [14] 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.[15] 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 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 $16.00/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 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 $41.00/hour. Therefore, for purposes of reporting on quality measures, we estimate an average labor cost of $41.00/hour.

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

[14] 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.

[15] 15 Id. at XV.

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 × $16/hour = $80.

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.[16] Preliminary estimates show that 252,567 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2013.[17]

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.

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 $205 per eligible professional ($41 per hour × 5 hours).

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it would take approximately 2.25 minutes to 108 minutes to perform all of the necessary reporting steps.

Per measure, at an average labor cost of $41/hour per practice, the cost associated with this burden will range from $0.17 to about $8.20 for more complicated cases and/or measures, with the cost for the median practice being $1.20. To report 9 measures, using an average labor cost of $41/hour, we estimated that the cost of reporting for an eligible professional via claims would range from $1.53 (2.25 minutes or 0.0375 hours × $41/hour) to $73.80 (108 minutes or 1.8 hours × $41/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 × 9 measures × 6 cases per measure) to 648 minutes (12 minutes per measure × 9 measures × 6 cases per measure), with the burden to the median practice being 94.5 minutes (1.75 minutes per measure × 9 measures × 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 $9.18 ($0.17 per measure × 9 measures × 6 cases per measure) to $442.80 ($8.20 per measure × 9 measures × 6 cases per measure), with the cost to the median practice being $64.58 per eligible professional ($1.20 per measure × 9 measures × 6 cases per measure).

[16] *Id.* at xvi. See Figure 4.

[17] *Id.*

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.[18] 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:

- 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.[19]

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.

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.[20] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[21] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[22] 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

[18] *Id.* at xvi. *See* Figure 4.

[19] *Id.* at xv.

[20] *Id.* at xv.

[21] *Id.* at xvi.

[22] *Id.* at 18.

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 $16 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 $96 ($16 per hour × 6 hours per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and are approved under OCN 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 $40 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $3,160.

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.*).

B. Summary of Proposed Burden Estimates

Table 59 summarizes this rule's proposed requirements and burden estimates.

TABLE 59—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS AND BURDEN

Regulation section(s)	OMB & CMS ID Nos.	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).	5 hr	1,250,000	41.00	51,250,000
			13,500,000 (reporting)*.	1.75 min	393,750	41.00	16,143,750
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

TABLE 59—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS AND BURDEN—Continued

Regulation section(s)	OMB & CMS ID Nos.	Respondents	Responses (total)	Burden (time) per response	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($)
CY 2015 PQRS (Group Practices Using the GPRO Web Interface).	0938–1059 (CMS–10276).	200	200 (self-nomination process).	6 hr	1,200	16.00	19,200
			200 (reporting)	79 hr	15,800	41.00	647,800
Total		630,770	14,130,970		2,496,855		81,259,510

* 13,500,000 = 250,000 × number of measures (9) × number of cases (6).
** There is no set cost. As explained above, the cost would 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 proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site 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.

We invite public comments on these potential information collection requirements. If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

PRA-specific comments must be received by September 2, 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. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Pathway for SGR Reform Act of 2013 and the PAMA. This proposed rule also is necessary to make changes to Part B payment policy for clinical diagnostic lab tests and other Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this proposed rule is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is

located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This proposed rule would impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing to implement a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2014 with proposed payment rates for CY 2015 using CY 2013 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the practitioner furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Lab Fee Schedule.

The annual update to the PFS conversion factor (CF) 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. We provide our most recent estimate of the SGR and physician update for CY 2015 on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/*.

The PAMA has replaced the reduction in the PFS update that would otherwise occur on January 1, 2015 with a zero percent update from January 1, 2015 to March 31, 2015. We estimate that, based upon the zero percent update and the adjustments necessary to maintain budget neutrality for the policies in this proposed rule the CF for this period will be $35.7977. Although the PAMA provides for a zero percent update for only the first 3 months of the year, the impacts in this proposed rule are based upon this CF being applicable throughout the year. However, in the absence of further Congressional action, the applicable update for the remainder of the year will be based on the statutory SGR formula and the CF will be adjusted accordingly.

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. While 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 permanently reform the SGR methodology for Medicare PFS updates.

Table 60 shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 60 (CY 2015 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 60:

- *Column A (Specialty)*: Identifies the specialty for which data is shown.
- *Column B (Allowed Charges)*: The aggregate estimated PFS allowed charges for the specialty based on CY 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 proposed changes in the work RVUs, including

the impact of changes due to potentially misvalued codes.

• *Column D (Impact of PE RVU Changes)*: This column shows the estimated CY 2014 impact on total allowed charges of the proposed changes in the PE RVUs.

• *Column E (Impact of RVU Changes)*: This column shows the estimated CY 2015 impact on total allowed charges of the proposed changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.

• *Column F (Combined Impact)*: This column shows the estimated CY 2015 combined impact on total allowed charges of all the proposed changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 60—CY 2015 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty (A)	Allowed charges (mil) (B)	Impact of work RVU changes (C)	Impact of PE RVU changes (D)	Impact of MP RVU changes (E)	Combined impact ** (F)
TOTAL	$87,374	0	0	0	0
ALLERGY/IMMUNOLOGY	215	0	0	0	0
ANESTHESIOLOGY	1,979	0	0	0	0
AUDIOLOGIST	60	0	0	−1	−1
CARDIAC SURGERY	351	0	0	−1	−1
CARDIOLOGY	6,420	0	0	0	1
CHIROPRACTOR	803	0	0	−1	−1
CLINICAL PSYCHOLOGIST	695	0	−1	0	−1
CLINICAL SOCIAL WORKER	514	0	−1	0	−1
COLON AND RECTAL SURGERY	158	0	0	0	0
CRITICAL CARE	285	0	0	0	1
DERMATOLOGY	3,162	0	0	0	0
DIAGNOSTIC TESTING FACILITY	705	0	−2	0	−2
EMERGENCY MEDICINE	3,024	0	0	1	1
ENDOCRINOLOGY	455	0	0	0	0
FAMILY PRACTICE	6,061	1	1	0	2
GASTROENTEROLOGY	1,875	0	0	0	0
GENERAL PRACTICE	498	0	0	0	0
GENERAL SURGERY	2,222	0	0	0	0
GERIATRICS	224	1	1	0	1
HAND SURGERY	159	0	0	0	0
HEMATOLOGY/ONCOLOGY	1,803	0	1	0	1
INDEPENDENT LABORATORY	703	0	3	0	3
INFECTIOUS DISEASE	647	0	0	0	1
INTERNAL MEDICINE	11,026	1	1	0	2
INTERVENTIONAL PAIN MGMT	672	0	1	0	1
INTERVENTIONAL RADIOLOGY	270	0	−1	0	−1
MULTISPECIALTY CLINIC/OTHER PHY	83	0	0	0	1
NEPHROLOGY	2,167	0	0	0	0
NEUROLOGY	1,502	0	0	0	0
NEUROSURGERY	733	0	0	1	1
NUCLEAR MEDICINE	48	0	0	0	1
NURSE ANES/ANES ASST	1,177	0	0	0	0
NURSE PRACTITIONER	2,201	0	0	0	1
OBSTETRICS/GYNECOLOGY	690	0	0	0	0
OPHTHALMOLOGY	5,663	0	0	−2	−2
OPTOMETRY	1,152	0	1	−1	0
ORAL/MAXILLOFACIAL SURGERY	44	0	0	0	0
ORTHOPEDIC SURGERY	3,649	0	0	0	0
OTHER	27	0	0	−1	−1
OTOLARNGOLOGY	1,167	0	0	0	0
PATHOLOGY	1,067	0	1	0	1
PEDIATRICS	58	0	0	0	0
PHYSICAL MEDICINE	998	0	0	0	0
PHYSICAL/OCCUPATIONAL THERAPY	2,806	0	0	1	1
PHYSICIAN ASSISTANT	1,553	0	0	0	1
PLASTIC SURGERY	368	0	0	−1	0
PODIATRY	1,979	0	0	0	0
PORTABLE X–RAY SUPPLIER	109	0	−3	0	−3
PSYCHIATRY	1,330	0	0	0	0
PULMONARY DISEASE	1,784	0	0	0	0
RADIATION ONCOLOGY	1,796	0	−4	0	−4
RADIATION THERAPY CENTERS	60	0	−8	0	−8
RADIOLOGY	4,497	0	−1	0	−2
RHEUMATOLOGY	538	0	0	0	0
THORACIC SURGERY	340	0	0	0	0
UROLOGY	1,829	0	0	0	0
VASCULAR SURGERY	970	0	0	0	1

* Table 60 shows only the payment impact on PFS services and does not include the effects of the change in the CF scheduled to occur on April 1, 2015 under current law.

** Column F may not equal the sum of columns C, D, and E due to rounding.

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 propose a payment rate for CCM services for CY 2015 in this proposed rule. Payment for this service at the proposed rate 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 to our proposal to implement 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. Radiation oncology and radiation treatment centers are negatively impacted by our proposal to treat radiation treatment vaults as indirect PE rather than direct PEs. Other impacts result from adjustments of PE RVUs for services as discussed in section II.B.

c. MP RVU Impacts

The changes in MP RVUs are primarily attributable to proposed changes as part of the statutorily required review of MP RVUs every five years as described in section II.C of this proposed rule. 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.

d. Combined Impact

Column F of Table 60 displays the estimated CY 2015 combined impact on total allowed charges by specialty of all the proposed 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 61 (Impact of Proposed Rule on CY 2015 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the proposed changes. We have included proposed 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 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 proposed rule.

TABLE 61—IMPACT OF PROPOSED RULE ON CY 2015 PAYMENT FOR SELECTED PROCEDURES

[Based on the March 2014 Preliminary Physician Update]

			Facility			Non-facility		
CPT [1]/HCPCS	MOD	Short Descriptor	CY 2014 [2]	CY 2015 Jan 1–March 31 [3]	Change	CY 2014 [2]	CY 2015 Jan 1–March 31 [3]	Change
11721		Debride nail 6 or more	$25.43	$25.42	0	$45.14	$45.46	1
17000		Destruct premalg lesion	53.38	52.98	−1	75.23	74.82	−1
27130		Total hip arthroplasty	1,394.94	1,397.90	0	NA	NA	NA
27244		Treat thigh fracture	1,261.68	1,269.03	1	NA	NA	NA
27447		Total knee arthroplasty	1,394.22	1,397.54	0	NA	NA	NA
33533		Cabg arterial single	1,955.92	1,930.93	−1	NA	NA	NA
35301		Rechanneling of artery	1,200.42	1,189.92	−1	NA	NA	NA
43239		Egd biopsy single/multiple	152.25	151.78	0	405.51	408.81	1
66821		After cataract laser surgery	324.55	314.66	−3	342.47	333.28	−3
66984		Cataract surg w/iol 1 stage	673.11	647.22	−4	NA	NA	NA
67210		Treatment of retinal lesion	523.37	506.18	−3	540.92	523.36	−3
71010		Chest x−ray 1 view frontal	NA	NA	NA	24.00	22.55	−6
71010	26	Chest x−ray 1 view frontal	9.31	9.31	0	9.31	9.31	0
77056		Mammogram both breasts	NA	NA	NA	116.07	164.31	42
77056	26	Mammogram both breasts	44.42	43.67	−2	44.42	43.67	−2
77057		Mammogram screening	NA	NA	NA	82.75	134.96	63
77057	26	Mammogram screening	35.82	35.08	−2	35.82	35.08	−2
77427		Radiation tx management x5	186.28	189.01	1	186.28	189.01	1
88305	26	Tissue exam by pathologist	38.33	38.30	0	38.33	38.30	0
90935		Hemodialysis one evaluation	73.44	73.39	0	NA	NA	NA
92012		Eye exam establish patient	54.81	52.98	−3	87.05	85.56	−2
92014		Eye exam&tx estab pt 1/>vst	82.75	80.54	−3	126.10	124.22	−1
93000		Electrocardiogram complete	NA	NA	NA	16.84	17.18	2
93010		Electrocardiogram report	8.60	8.59	0	8.60	8.59	0
93015		Cardiovascular stress test	NA	NA	NA	75.94	76.61	1
93307	26	Tte w/o doppler complete	45.85	46.18	1	45.85	46.18	1
93458	26	L hrt artery/ventricle angio	325.63	320.03	−2	325.63	320.03	−2
98941		Chiropract manj 3–4 regions	35.46	35.08	−1	41.55	41.17	−1
99203		Office/outpatient visit new	77.02	77.32	0	108.18	108.47	0
99213		Office/outpatient visit est	51.58	51.55	0	73.08	73.39	0
99214		Office/outpatient visit est	79.17	79.11	0	107.83	108.11	0

TABLE 61—IMPACT OF PROPOSED RULE ON CY 2015 PAYMENT FOR SELECTED PROCEDURES—Continued

[Based on the March 2014 Preliminary Physician Update]

			Facility			Non-facility		
CPT [1]/HCPCS	MOD	Short Descriptor	CY 2014 [2]	CY 2015 Jan 1–March 31 [3]	Change	CY 2014 [2]	CY 2015 Jan 1–March 31 [3]	Change
99222		Initial hospital care	138.63	138.18	0	NA	NA	NA
99223		Initial hospital care	204.19	204.40	0	NA	NA	NA
99231		Subsequent hospital care	39.41	39.38	0	NA	NA	NA
99232		Subsequent hospital care	72.36	73.03	1	NA	NA	NA
99233		Subsequent hospital care	104.24	104.89	1	NA	NA	NA
99236		Observ/hosp same date	219.24	219.80	0	NA	NA	NA
99239		Hospital discharge day	107.47	108.47	1	NA	NA	NA
99283		Emergency dept visit	61.97	62.29	1	NA	NA	NA
99284		Emergency dept visit	118.22	119.21	1	NA	NA	NA
99291		Critical care first hour	224.61	225.53	0	274.76	276.72	1
99292		Critical care addl 30 min	112.48	112.76	0	123.23	123.86	1
99348		Home visit est patient	NA	NA	NA	84.54	84.48	0
99350		Home visit est patient	NA	NA	NA	178.40	177.91	0
G0008		Immunization admin	NA	NA	NA	25.08	25.42	1

[1] CPT codes and descriptions are copyright 2013 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
[2] The CY 2014 CF is 35.8228.
[3] Payments based on the CY 2014 CF of 35.8228, adjusted to 35.7977 to include the budget neutrality adjustment and the zero percent update in the CF required by PAMA.

D. Effect of Proposed Changes in Telehealth List

As discussed in section II.E. of this proposed rule, we are proposing to add several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the proposed additions.

E. Effect of Proposed Changes in Geographic Practice Cost Indices (GPCIs)

As discussed in section II.D of this proposed rule, 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 proposing 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.E. 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 Proposed 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 proposing only to correct the dates in the Code of Federal Regulations (CFR) at 42 CFR 414.610(c)(1)(ii) and 42 CFR 414.610(c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

The geographic designations for approximately 99.48 percent of ZIP codes would be unchanged if we adopt OMB's revised statistical area delineations and the updated RUCA codes. There are a similar number of ZIP codes that would change from rural to urban (122, or 0.28 percent) and from urban to rural (100, or 0.23 percent). In general, if we adopt OMB's revised delineations and the updated RUCA codes, it is expected that ambulance providers and suppliers in 100 ZIP codes within 11 states may experience payment increases while ambulance providers and suppliers in 122 ZIP codes within 22 states may experience payment decreases. None of the current ''Super Rural Bonus'' areas would lose their status if we adopt 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 minimal fiscal impact on the Medicare program because payments would, in effect, be redistributed.

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.

5. Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests

The Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests in section III.F of this proposed rule would not impact CY 2015 physician payments under the PFS.

6. Private Contracting/Opt Out

We are correcting cross-references and outdated terminology in the regulations that we inadvertently neglected to revise, and proposing a change in the appeals process to be 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 are soliciting public comments regarding substitute physician billing arrangements. Since we are not proposing 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 proposed rule would not impact CY 2015 physician payments under the PFS.

9. Physician Compare

There will be no impact for the Physician Compare Web site because we are not collecting any information for the Physician Compare Web site.

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.''[23] 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, 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.[24] 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 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.[25] Preliminary estimates show that 252,567 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2013.[26] According to the historical data cited above, although the claims-based reporting mechanism is still the most widely-used reporting mechanism, we are seeing a decline in the use of the claims-based reporting mechanism in the PQRS. 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 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.[27] 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 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 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.[28] We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will steadily increase as

[23] 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.

[24] Id. at XV.

[25] *Id.* at xvi. *See* Figure 4.

[26] *Id.*

[27] *Id.* at xvi. *See* Figure 4.

[28] *Id.* at xv.

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.[29] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[30] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[31] 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 (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 proposing 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.

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 × $16/hour = $80.

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 and Group Practices: 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

[29] *Id.* at xv.

[30] *Id.* at xvi.

[31] *Id.* at 18.

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 $205 per eligible professional ($41 per hour × 5 hours).

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it would take approximately 2.25 minutes to 108 minutes to perform all the steps necessary to report 9 measures.

Per measure, at an average labor cost of $41/hour per practice, the cost associated with this burden will range from $0.17 in labor to about $8.20 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.20. To report 9 measures, using an average labor cost of $41/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from $1.53 (2.25 minutes or 0.0375 hours × $41/hour) to $73.80 (108 minutes or 1.8 hours × $41/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 × 9 measures × 6 cases per measure) to 648 minutes (12 minutes per measure × 9 measures × 6 cases per measure), with the burden to the median practice being 94.5 minutes (1.75 minutes per measure × 9 measures × 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 $9.18 ($0.17 per measure × 9 measures × 6 cases per measure) to $442.80 ($8.20 per measure × 9 measures × 6 cases per measure), with the cost to the median practice being $64.58 per eligible professional ($1.20 per measure × 9 measures × 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 62 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 $16 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 $96 ($16 per hour × 6 hours per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and was approved under OMB control number 0938–0941—Form 10136, with an expiration date of December 31, 2011 for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice 79 hours to submit quality measures data via the GPRO web interface at a cost of $40 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $3,160.

Tables 62 and 63 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 62—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS AND/OR GROUP PRACTICES USING THE CLAIMS, QUALIFIED REGISTRY, AND EHR-BASED REPORTING MECHANISMS

	Minimum burden estimate	Maximum burden estimate
Estimated Annual Burden Hours for Claims-based Reporting (for individual eligible professionals only)	1,201,543	3,633,006.40
Estimated Annual Burden 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	2,985,238	5,416,701.40
Estimated Cost for Claims-based Reporting (for individual eligible professionals only)	$53,545,000	$161,875,000
Estimated Cost for Qualified registry-based Reporting	$54,681,495	$54,681,495
Estimated Cost for EHR-based Reporting	$16,400,000	$16,400,000
Estimated Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	$124,626,495	$232,956,495

TABLE 63—ESTIMATED COSTS PER VENDOR TO PARTICIPATE IN THE PQRS

	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	$96
Estimated Cost Per Group Practice to Report Quality Measures	$3,160
Estimated Total Annual Cost Per Group Practice	$3,256
Annual Burden Cost for Group Practices	$651,200

11. EHR Incentive Program

The changes to the EHR Incentive Program in section III.L of this proposed rule 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 revisit the current quality performance standard, propose changes to the quality measures, propose modifications to the timeframe between updates to the quality performance benchmarks, and propose to establish an additional incentive to reward ACO quality improvement. Since the proposed policies are not expected to increase the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants, there is no impact for these proposals.

13. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a 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 proposed changes to the VM in section III.N of this proposed rule would 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. Category 2 includes groups that do not fall within either of the two subcategories (a) or (b) of Category 1. 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 64.

TABLE 64—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 64 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.

At the time of this proposed rule, we have not 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. Therefore, in this proposed rule, we present estimates 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 will be available on the CMS Web site 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''. We will update this section in the CY 2015 final rule with comment period based on CY 2013 data that will be used to calculate the value-based payment modifier in CY 2015. The impact of the policies for the CY 2017 VM proposed in this rule, if finalized, would be discussed in the PFS rule for CY 2017.

Please note that we are not able to determine which groups would fall in Category 1 and Category 2, as described above, using CY 2012 claims data. Therefore, the 2012 estimates that we present in this section are based on groups for which we produced a 2012 QRUR and for whom the quality or cost composite could be calculated. Based on our simulation of the 1,032 groups with 100 or more eligible professionals for which we produced a 2012 QRUR and for whom the quality or cost composite could be calculated, the vast majority of groups (81.0 percent) are in the average quality and average cost tiers (this

includes groups missing either the quality or cost composite score, who are assigned to average quality or average cost). The simulation also found that approximately 8 percent of groups are in tiers that would receive an upward adjustment, resulting in a payment incentive of between +1.0x and +2.0x percent; and approximately 10.4 percent of groups are in tiers that would receive a downward adjustment of between -0.5 and -1.0 percent to payments under Medicare PFS (Table 65).

TABLE 65—SIMULATED DISTRIBUTION USING 2012 DATA OF QUALITY AND COST TIERS FOR GROUPS WITH 100 OR MORE ELIGIBLE PROFESSIONALS FOR WHICH A QUALITY OR COST COMPOSITE SCORE COULD BE CALCULATED (1,032 GROUPS)

Cost/quality	Low quality (percent)	Average quality (percent)	High quality (percent)
Low Cost	0.5	3.3	0.7
Average Cost	4.4	81.0	4.0
High Cost	3.6	2.4	0.2

In 2013, 136 groups with 100 or more eligible professionals elected to have their CY 2015 VM calculated using the quality-tiering methodology; therefore, these groups will receive an upward, neutral, or downward adjustment based on the calculation of their quality and cost composites. The VM for groups with 100 or more eligible professionals that did not elect quality tiering and self-nominated for the PQRS as a group and reported at least one measure or elected the PQRS administrative claims option will be 0.0 percent, meaning that these groups will not receive a payment adjustment under the VM in CY 2015.

Please note that in CY 2015, only the physicians in groups with 100 or more eligible professionals that are in Category 1 and elect quality-tiering will be subject to upward, downward, or no payment adjustment under the VM according to Table 64. Additionally, physicians in groups with 100 or more eligible professionals that fall in Category 2 will be subject to the -1.0 percent value-modifier payment adjustment in CY 2015. In the CY 2015 final rule with comment period, we will present the actual number of groups and physicians that will be subject to the VM in CY 2015.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

H. Impact on Beneficiaries

There are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, we believe that many of the proposed changes, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the VM 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 the five year review of MPRVUs; 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 proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 61, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $77.02, which means that in CY 2014 a beneficiary would be responsible for 20 percent of this amount, or $15.40. Based on this proposed rule, using the current (CY 2014) CF of $35.8228, adjusted to $35.7997 to include budget neutrality, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 61, is $77.32, which means that, in CY 2015, the proposed beneficiary coinsurance for this service would be $15.46.

In section II.H, we propose to define colorectal cancer screening to include the anesthesia associated with the procedure. If this proposal is adopted, there would be no beneficiary coinsurance or deductible applied to anesthesia associated with screening colonoscopy even when the anesthesia is furnished by a different practitioner than the one who furnishes the procedure.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 66 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 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 66—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2015 Annualized Monetized Transfers	Estimated decrease in expenditures of $1.1 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 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 67—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfers
CY 2015 Annualized Monetized Transfers of beneficiary cost coinsurance.	$9 million.
From Whom to Whom?	Federal Government to Beneficiaries.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial ''Regulatory Flexibility Analysis.'' The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 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 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 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 proposes to amend 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. Section 403.902 is amended by removing the definition of ''Covered device''.

■ 3. Section 403.904 is amended by—

■ a. Revising paragraphs (c)(8) and (d)(3) and (4).

■ b. Adding paragraphs (d)(5) and (6).

■ c. Removing paragraph (g).

■ d. Redesignating paragraphs (h) and (i) as paragraphs (g) and (h), respectively.

The revisions and additions read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

* * * * *

(c) * * *

(8) *Related covered and non-covered drug, device, biological or medical supply.* Report the marketed name of the related covered and non-covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-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) For devices and medical supplies, applicable manufacturers may also report the therapeutic area or product category for the device 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.

* * * * *

■ 4. New subparts J and K are added to part 403 to read as follows:

Subpart J—[Reserved]

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 J—[Reserved]

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 title 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

■ 5. 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).

■ 6. Section 405.400 is amended by revising the definition of ''Emergency care services'' to read as follows:

§ 405.400 Definitions.

* * * * *

Emergency care services means ''emergency services'' as that term is defined in § 424.101 of this chapter.

* * * * *

§ 405.420 [Amended]

■ 7. Section 405.420 is amended in paragraph (e) by removing the phrase ''Medicare+Choice'' and adding in its place the phrase ''Medicare Advantage''.

§ 405.425 [Amended]

■ 8. Section 405.425 is amended in paragraph (a) by removing the phrase ''Medicare+Choice'' and adding in its place the phrase ''Medicare Advantage''.

§ 405.450 [Amended]

■ 9. Section 405.450 is amended by—

■ a. In paragraph (a) removing the reference ''405.803'' and adding in its place the reference ''498.3(b)''.

■ b. In paragraph (b) removing the reference ''405.803'' and adding in its place ''405.924''.

§ 405.455 [Amended]

■ 10. Section 405.455 is amended by—

■ a. In the section heading removing the phrase ''Medicare+Choice'' and adding in its place the phrase ''Medicare Advantage''.

■ b. In the introductory text removing the phrase ''Medicare+Choice (M+C)'' and adding in its place the phrase ''Medicare Advantage''.

■ 11. 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.

* * * * *

■ 12. Section 405.2413 is amended by—

■ a. In paragraph (a)(4) removing '';'' and 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.

* * * * *

■ 13. Section 405.2415 is amended by—

■ a. Revising the section heading and paragraph (a)(5).

■ b. In paragraph (a)(4) removing '';'' and adding in its place ''; and''.

■ c. 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.

* * * * *

■ 14. Section 405.2452 is amended by—

■ a. In paragraph (a)(4) removing '';'' and 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.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 15. 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.

■ 16. Section 410.26 is amended by revising paragraphs (b)(5) and (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.

* * * * *

■ 17. 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.

* * * * *

■ 18. 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.

* * * * *

■ 19. 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.

* * * * *

■ 20. 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.

* * * * *

■ 21. 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 Web site.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 22. 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)).

■ 23. 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.* 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 in order 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.

* * * * *

■ 24. Section 414.90 is amended by—

■ a. Removing the phrase ''CG CAHPS'' and adding in its place the phrase ''CAHPS for PQRS'' everywhere it appears.

■ b. Removing the phrase ''CAHPS'' and adding in its place the phrase ''CAHPS for PQRS'' everywhere it appears.

■ c. In paragraph (b) revising the definition of ''Measures group''.

■ d. Revising paragraphs (j)(4) and (m)(1) and (3).

■ e. Adding paragraphs (j)(6) and (k)(4).

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 2 measures contained in the proposed 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. Of the 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 2 measures contained in the cross-cutting measure set. Measures with a 0 percent performance rate would not be counted.

(*ii*) [Reserved]

(*2*) [Reserved]

(*B*) [Reserved]

(ii) *Via qualified registry.* (A) For the 12-month 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 2 measures contained in the proposed 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. Of the 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 2 measures contained in the cross-cutting measure set.

(*ii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(*B*) [Reserved]

(iii) *Via EHR direct product*. For the 12-month 2017 PQRS payment adjustment reporting period, 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 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 CEHRT 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.

* * * * *

(6) *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 or more eligible professionals, report on all measures included in the Web interface and populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then 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 or more 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 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 the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 2 measures contained in the cross-cutting measure set. Measures with a 0 percent performance rate would not be counted; or

(iii) *Via EHR direct product*. For a group practice of 2 or more 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 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 Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor*. For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a 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 Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry*. For a group practice of 25 or more eligible professionals, 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 6 measures. Of these 6 measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set.

(vi) *Via a certified survey vendor in addition a direct EHR product or EHR data submission vendor*. 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 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 that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 6 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.

(vii) *Via a certified survey vendor in addition to the GPRO Web interface*. (A) For a group practice of 25 to 99 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 would be required to report on at least 1 measure for which there is Medicare patient data.

(B) For a group practice of 100 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, 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.

(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 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, or efficiency/appropriate use.

(ii) [Reserved]

* * * * *

(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 30 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 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 on an ad-hoc basis.

(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]

■ 25. Section 414.511 is removed.

■ 26. 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.

* * * * *

■ 27. 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.

* * * * *

■ 28. 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 TIN with 1 eligible professional as identified by an individual 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.

■ 29. Section 414.1210 is amended by—

■ a. Adding paragraphs (a)(3) and (b)(2), (3), and (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 and eligible professionals in groups with 2 or more eligible professionals and to physicians and eligible professionals who are solo practitioners based on the performance period described at § 414.1215(c).

(b) * * *

(2) For the CY 2017 payment adjustment period and each subsequent payment adjustment period, the value-based payment modifier is applicable to physicians and eligible professionals in groups with 2 or more eligible professionals and to physicians and eligible professionals who are solo practitioners that participate in the Shared Savings Program. The value-based payment modifier for groups and solo practitioners that participate in the Shared Savings Program during the payment adjustment period is determined based on paragraphs (b)(2)(i) through (iv) of this section. For groups and solo practitioners that participate in the Shared Savings Program during the performance period, but do not participate in the Shared Savings Program during the payment adjustment period, the quality composite is classified as ''average'' under § 414.1275(b)(1) and the cost composite score is calculated under § 414.1260(b) based on performance on the cost measures identified under § 414.1235 during the performance period.

(i) The cost composite is classified as ''average'' under § 414.1275(b)(2) for the payment adjustment period.

(ii) The quality composite score is calculated under § 414.1260(a) using quality data from the ACO in which the groups and solo practitioners participate during the payment adjustment period, as collected under § 425.500 of this chapter for the performance period.

(iii) If the ACO did not exist during the performance period, then the quality composite for the groups and solo

practitioners is classified as ''average'' under § 414.1275(b)(1) for the payment adjustment period.

(iv) The same value-based payment modifier applies to all groups and solo practitioners participating in an ACO during the payment adjustment period.

(3) For the CY 2017 payment adjustment period and each subsequent payment adjustment period, the value-based payment modifier is applicable to physicians and eligible professionals in groups with 2 or more eligible professionals and to physicians and eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during 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 and do not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period is determined based on paragraphs (b)(3)(i) through (iv) of this section.

(i) If a group reports under PQRS GPRO for the performance period and meets the criteria for satisfactory reporting for the PQRS payment adjustment, then the quality composite score is calculated under § 414.1260(a) based on the PQRS GPRO quality data, and the cost composite score is calculated under § 414.1260(b) based on performance on the cost measures identified under § 414.1235 during the performance period. If the group fails to meet the criteria for satisfactory reporting, then the group is in Category 2 and receives a downward adjustment under the value-based payment modifier for the payment adjustment period equal to the percentage applied for high cost/low quality under § 414.1275(c).

(ii) If a group is composed of one or more eligible professionals that participate in the Pioneer ACO Model or CPC Initiative and others who do not participate, and at least 50 percent of all eligible professionals in the group satisfactorily report quality data to CMS for the performance period, then the quality composite score is calculated under § 414.1260(a) based on the quality data reported under PQRS by individual eligible professionals in the group, and the group receives the higher of ''average quality'' or the actual classification under § 414.1275(b)(1), and the cost composite score is calculated under § 414.1260(b) based on performance on the cost measures identified under § 414.1235 during the performance period. If less than 50 percent of all eligible professionals in the group satisfactorily report quality data to CMS for the performance period, then the group is in Category 2 and receives a downward adjustment under the value-based payment modifier for the payment adjustment period equal to the percentage applied for high cost/low quality under § 414.1275(c).

(iii) If a group is composed entirely of eligible professionals that participate in the Pioneer ACO Model or CPC Initiative, and the group successfully reports quality data to the Pioneer ACO Model or CPC Initiative for the performance period, then the quality composite is classified as ''average'' under § 414.1275(b)(1), and the cost composite score is calculated under § 414.1260(b) based on performance on the cost measures identified under § 414.1235 during the performance period. If the group fails to successfully report quality data to the Pioneer ACO Model or the CPC Initiative for the performance period, then the group is in Category 2 and receives a downward adjustment under the value-based payment modifier for the payment adjustment period equal to the percentage applied for high cost/low quality under § 414.1275(c).

(iv) If a solo practitioner successfully reports quality data to the Pioneer ACO Model or CPC Initiative for the performance period, then the quality composite is classified as ''average'' under § 414.1275(b)(1), and the cost composite score is calculated under § 414.1260(b) based on performance on the cost measures identified under § 414.1235 during the performance period. If the solo practitioner fails to successfully report quality data to the Pioneer ACO Model or the CPC Initiative for the performance period, then the solo practitioner is in Category 2 and receives a downward adjustment under the value-based payment modifier for the payment adjustment period equal to the percentage applied for high cost/low quality under § 414.1275(c).

(v) For groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period and participate in other similar Innovation Center models or CMS initiatives during the payment adjustment period (but not the Shared Savings Program), the quality composite is determined based on paragraphs (b)(3)(i) through (iv) of this section for the payment adjustment period. The cost composite is classified as ''average'' under § 414.1275(b)(2) for the payment adjustment period.

(4) For the CY 2017 payment adjustment period and each subsequent payment adjustment period, the value-based payment modifier is applicable to physicians and eligible professionals in groups with 2 or more eligible professionals and to physicians and eligible professionals who are solo practitioners that participate in other similar Innovation Center models or CMS initiatives during the performance period. The quality composite and cost composite are determined based on paragraphs (b)(3)(i) through (v) of this section.

(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]

■ 30. Section 414.1220 is amended by removing the phrase ''Groups of physicians'' and adding in its place the phrase ''Solo practitioners and groups''.

■ 31. 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.

■ 32. 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]

■ 33. Section 414.1235 is amended in paragraph (a) introductory text by removing the phrase ''of physicians subject'' and add in its place the phrase ''and solo practitioners subject''.

■ 34. 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]

■ 35. Section 414.1245 is amended in the introductory text by removing the phrase ''of physicians subject'' and adding in its place the phrase ''and solo practitioner subject''.

■ 36. Section 414.1250 is amended by revising paragraph (a) to read as follows:

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, 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.

* * * * *

■ 37. 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.

■ 38. Section 414.1265 is amended by—

■ a. In the introductory text, removing the phrase ''of physicians subject'' and add in its place the phrase ''or solo practitioner subject''.

■ b. Revising paragraph (a)

The addition reads as follows:

§ 414.1265 Reliability of measures.

* * * * *

(a) In a performance period, if a group or a 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 paragraph (a) of this section is the all-cause hospital readmission 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 readmission measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(2) [Reserved]

* * * * *

■ 39. Section 414.1270 is amended by adding paragraph (c) to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(c) For the CY 2017 payment adjustment period:

(1) A downward payment adjustment of −4.0 percent will be applied to a group and a solo practitioner 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).

(3) For a group comprised of between 2 and 9 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), except that such adjustment will be 0.0 percent if the group and the solo practitioner are determined to be low quality/high cost, low quality/average cost, or average quality/high cost.

(4) If all of the eligible professionals in a group and a solo practitioner subject to the value-based payment modifier participate as individuals in the PQRS using a qualified clinical data registry or any other reporting mechanism available to them, and CMS is unable to receive quality performance data for those eligible professionals and the solo practitioner under that reporting mechanism, the quality composite score for such group and solo practitioner 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.

■ 40. Section 414.1275 is amended by—

■ a. Revising paragraph (a).

■ b. Redesignating paragraphs (d), (d)(1), and (d)(2) as paragraphs (d)(1), (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:

CY 2017—VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Cost/quality	Low quality (percent)	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.

(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); and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +3x (rather than +2x).

§ 414.1285 [Amended]

■ 41. Section 414.1285 is amended by removing the phrase ''of physicians may'' and adding in its place the phrase ''and a solo practitioner may''.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 42. 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).

■ 43. 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%.''

■ c. Revising paragraph (a)(2).

■ d. Adding paragraphs (a)(3) and (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 measure introduced during an ACO's agreement period is set at the level of complete and accurate reporting for the first performance year for which reporting of the measure is required. For subsequent performance years, 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 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.

* * * * *

(e) * * *

(4) (i) ACOs that demonstrate quality improvement on established quality measures from year to year will be eligible for up to 2 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 two 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.

■ 44. 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 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

■ 45. 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).

■ 46. Section 498.3 is amended by adding paragraph (b)(19) to read as follows:

§ 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.

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Dated: June 13, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 19, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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