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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.
Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 423, and 425

[CMS–1600–P]

RIN 0938–AR56

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1600–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 *http://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–1600–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–1600–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:

Chava Sheffield, (410) 786–2298, for issues related to practice expense methodology and impacts.

Ryan Howe, (410) 786–3355, for issues related to direct practice expense inputs and telehealth services.

Joanna Baldwin, (410) 786–7205, for issues related to misvalued services.

Ken Marsalek, (410) 786–4502, for issues related to the multiple procedure payment reduction.

Heidi Oumarou, (410) 786–7942, for issues related to the revision of Medicare Economic Index (MEI).

Roberta Epps, (410) 786–4503, for issues related to chiropractors billing for evaluation and management services.

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

Simone Dennis, (410) 786–8409, for issues related to therapy caps.

Darlene Fleischmann, (410) 786–2357, for issues related to ''incident to'' services.

Corinne Axelrod, (410) 786–5620, for issues related to ''incident to'' services in Rural Health Center s or Federally Qualified Health Centers.

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

Sandra Adams, (410) 786–2982, for issues related to Medicare shared savings program.

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 and EHR incentive program.

Ronke Fabayo, (410) 786–4460 or Jay Blake, (410) 786–9371, for issues related to individual liability for payments made to providers and suppliers and handling of incorrect payments.

Rosemarie Hakim, (410) 786–3934, for issues related to coverage of items and services furnished in FDA-approved investigational device exemption clinical trials.

Jamie Hermansen, (410) 786–2064 or Jyme Schafer, (410) 786–4643, for issues related to ultrasound screening for abdominal aortic aneurysms.

Pauline Lapin, (410)786–6883, for issues related to the chiropractic services demonstration budget neutrality issue.

Andrew Morgan, (410) 786–2543, for issues related to e-prescribing under Medicare Part D.

Michael Wrobleswki, (410) 786–4465, for issues related to value-based modifier and improvements to physician feedback.

Elliot Isaac, (410) 786–4735, for malpractice RVUs and for any physician payment issue not identified above.

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:

AMA RUC American Medical Association/[Specialty Society] Relative [Value] Update Committee
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)
CAH Critical access hospital
CF Conversion factor
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2012 American Medical Association. All rights reserved.*)
CY Calendar year
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
eRx Electronic prescribing
FFS Fee-for-service
FR **Federal Register**
GPCI Geographic practice cost index
HCPCS Healthcare Common Procedure Coding System
MCTRJCA Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96)
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIEA–TRHCA The Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act (Pub. L. 109–432)
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MP Malpractice
MPPR Multiple procedure payment reduction
MMEA Medicare and Medicaid Extenders Act (Pub. L. 111–309)
MMSEA Medicare, Medicaid, and State Children's Health Insurance Program Extension Act (Pub. L. 110–73)
NPP Nonphysician practitioner
OBRA '89 Omnibus Budget Reconciliation Act of 1989
OBRA '90 Omnibus Budget Reconciliation Act of 1990
PC Professional component
PE Practice expense
PE/HR Practice expense per hour
PFS Physician Fee Schedule
PQRS Physician Quality Reporting System
RFA Regulatory Flexibility Act
RIA Regulatory impact analysis
RVU Relative value unit
SGR Sustainable growth rate
TAP Technical Advisory Panel
TC Technical component
TPTCCA Temporary Payroll Tax Cut Continuation Act (Pub. L. 112–78)
VBP Value-based purchasing

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 with comment period are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. 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 2014 PFS proposed rule, refer to item CMS–1600–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 Elliot Isaac at (410) 786–4735.

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 2012 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 2014.

2. Summary of the Major Provisions

The Social Security Act (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 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 2014 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.
- Applying Therapy Caps to Outpatient Therapy Services Furnished by CAHs.
- Requiring the Compliance with State law as a Condition of Payment for Services Furnished Incident to Physician and Other Practitioner Services.
- Revising the MEI based on MEI TAP Recommendations.

• Updating the Ambulance Fee Schedule regulations.
• Updating the—
++ Physician Compare Web site.
++ Physician Quality Reporting System.
++ Electronic Health Record (EHR) Incentive Program.
++ Medicare Shared Savings Program.
• Budget Neutrality for the Chiropractic Services Demonstration.
• Physician Value-Based Payment Modifier and the Physician Feedback Reporting 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. For most specialties the projected impacts are a small percentage change in Medicare payments under the PFS. For a few specialties a larger impact is projected. Diagnostic Testing Facilities, Independent Laboratory, Pathology, Radiation Oncology, and Radiation Therapy Centers are projected to have a change of 5 percent or more.

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 then 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 (OBRA '89) (Pub. L. 101–239, enacted on December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90 (Pub. L. 101–508, enacted on November 5, 1990). 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 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 physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician 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.

We establish work RVUs for new and revised codes based, in part, on our review of recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC).

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. Originally, this new method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997) 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 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 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 (BBRA) (Pub. L. 106–113, enacted on November 29, 1999) 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 malpractice insurance premium data collected from commercial and physician-owned insurers from all the states, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review all 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.

While refinements to the direct PE inputs initially relied heavily on input from the AMA 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.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA 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 with an emphasis on seven specific categories (see section II.B.2. of this proposed rule).

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.E.2 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. A more detailed discussion of the calculation of the CF, the SGR, and the MEI appears in the PFS final rule with comment period for each calendar year (the most recent begins on 77 FR 69131).

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 2013 PFS final rule with comment period (77 FR 68892) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2012 interim RVUs and established interim RVUs for new and revised codes for CY 2013 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 certain statutory provisions including provisions of the Affordable Care Act (Pub. L. 111–148) and the Middle Class Tax Relief and Jobs Creation Act (MCTRJCA) (Pub. L. 112–96), including claims-based data reporting requirements for therapy services.

In the CY 2013 PFS final rule with comment period, we announced the following for CY 2013: The total PFS update of -26.5 percent; the initial estimate for the sustainable growth rate (SGR) of -19.7 percent; and the CY 2013 CF of $25.0008. These figures were calculated based on the statutory provisions in effect on November 1, 2012, when the CY 2013 PFS final rule with comment period was issued.

On January 2, 2013, the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112–240) was signed into law. Section 601(a) of the ATRA specified a zero percent update to the PFS CF for CY 2013. As a result, the CY 2013 PFS conversion factor was revised to $34.0320. In addition, the ATRA extended and added several provisions affecting Medicare services furnished in CY 2013, including:

- Section 602—extending the 1.0 floor on the work geographic practice cost index through CY 2013;
- Section 603—extending the exceptions process for outpatient therapy caps through CY 2013, extending the application of the cap and manual medical review threshold to services furnished in the hospital outpatient department (OPD) through CY 2013, and requiring the counting of a proxy amount for therapy services

furnished in a Critical Access Hospital (CAH) toward the cap and threshold during CY 2013.

In addition to the changes effective for CY 2013, section 635 of ATRA revised the equipment utilization rate assumption for advanced imaging services furnished on or after January 1, 2014.

On March 5, 2013, we submitted to the Medicare Payment Advisory Committee (MedPAC) an estimate of the SGR and CF applicable to Medicare payments for physicians' services for CY 2014, as required by section 1848(d)(1)(E) of the Act. The actual values used to compute physician payments for CY 2014 will be based on later data and are scheduled to be published by November 1, 2013 as part of the CY 2014 PFS final rule with comment period.

II. Provisions of the Proposed Rule for PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103–432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act to require us to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect physician 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. In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have otherwise been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. 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, equipment, and supplies) 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 based on our review of recommendations received from the AMA RUC. 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 (75 percent old/25 percent new for CY 2010, 50 percent old/50 percent new for CY 2011, 25 percent old/75 percent new for CY 2012, and 100 percent new for CY 2013) 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 in CY 2013. Therefore, the CY 2014 PE RVUs 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 survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments 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 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.

We do not use the PPIS data for sleep medicine since there is not a full year of Medicare utilization data for that specialty given the specialty code was only available beginning in October 1, 2012. We anticipate using the PPIS data to create PE/HR for sleep medicine for CY 2015 when we will have a full year of data to make the calculations.

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 physician 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 described 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 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 PC and TC components that can be billed separately, the payment for the global service equals the sum of the payment for the TC and PC. This is a result of using 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 current aggregate pool of direct PE costs. This is the product of the current aggregate PE (aggregate direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data.

Step 3: Calculate the aggregate pool of direct costs. This is the sum of the product of the direct costs for each service from Step 1 and the utilization data for that service. For CY 2014, we adjusted the direct cost pool to match the new PE share of the MEI, as discussed in section II.D. of this rule.

Step 4: Using the results of Step 2 and Step 3 calculate a direct PE scaling adjustment so that the aggregate direct cost pool does not exceed the current aggregate direct cost pool and apply it to the direct costs from Step 1 for each service.

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 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 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 percentage (direct PE RVUs/direct percentage) + clinical PE RVUs.

Note: For global services, the indirect 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 5, 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. For CY 2014, we adjusted the indirect cost pool to match the new PE share of the MEI, as discussed in section II.D. of this rule.

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 physician 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 and the MEI revision adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs (prior to the MEI revision adjustment and the OPPS/ASC cap redistribution). 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 all specialties are included for purposes of calculating the final BN adjustment. (See ''Specialties excluded from ratesetting calculation'' later in this section.) As discussed in section II.D. of this proposed rule, we are revising the Medicare Economic Index (MEI) for CY 2014.

Step 19: Consistent with the proposed policy addressed in section II.A.4. of this proposed rule, apply the OPPS/ASC cap to codes subject to the cap and redistribute the RVU reduction to the PE RVUs for all other services.

(5) Setup File Information

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

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthestist.
57	Individual certified prosthetist-orthotist.
58	Individuals not included in 55, 56, or 57.
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.
95	Competitive Acquisition Program (CAP) Vendor.
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.
1	Supplier of oxygen and/or oxygen related equipment.
2	Pedorthic personnel.
3	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 physician 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 physician time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.

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

Modifier	Description	Volume adjustment	Time adjustment
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

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

For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs, and therefore, includes all adjustments. A time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where time units are duplicative.

- *Work RVUs:* The setup file contains the work RVUs from this 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 expensive diagnostic imaging equipment, which is equipment priced at over $1 million (for example, computed tomography (CT) and magnetic resonance imaging (MRI) scanners), we use an equipment utilization rate assumption of 75 percent. Section 1848(b)(4)(C) of the Act, as modified by section 635 of the America Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted on January 2, 2013) (ATRA), requires that for fee schedules established for CY 2014 and subsequent years, in the methodology for determining PE RVUs for expensive diagnostic imaging equipment, the Secretary shall use a 90 percent assumption. The provision also requires that the reduced expenditures attributable to this change in the utilization rate for CY 2014 and subsequent years shall not be taken into account when applying the BN limitation on annual adjustments described in section 1848(c)(2)(B)(ii)(II) of the Act. We are applying the 90 percent utilization rate assumption in CY 2014 to all of the services to which the 75 percent equipment utilization rate assumption applied in CY 2013. These services are listed in a file called ''CY 2014 CPT Codes Subject to 90 Percent Usage Rate,'' available on the CMS Web site under downloads for the CY 2014 PFS proposed rule at *http://www.cms.gov/physicianfeesched/downloads/*. These codes are also displayed in Table 3.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION

CPT code	Short descriptor
70336 ..	Mri, temporomandibular joint(s).
70450 ..	Ct head/brain w/o dye.
70460 ..	Ct head/brain w/dye.
70470 ..	Ct head/brain w/o & w/dye.
70480 ..	Ct orbit/ear/fossa w/o dye.
70481 ..	Ct orbit/ear/fossa w/dye.
70482 ..	Ct orbit/ear/fossa w/o & w/dye.
70486 ..	Ct maxillofacial w/o dye.
70487 ..	Ct maxillofacial w/dye.
70488 ..	Ct maxillofacial w/o & w/dye.
70490 ..	Ct soft tissue neck w/o dye.
70491 ..	Ct soft tissue neck w/dye.
70492 ..	Ct soft tissue neck w/o & w/dye.
70496 ..	Ct angiography, head.
70498 ..	Ct angiography, neck.
70540 ..	Mri orbit/face/neck w/o dye.
70542 ..	Mri orbit/face/neck w/dye.
70543 ..	Mri orbit/face/neck w/o & w/dye.
70544 ..	Mr angiography head w/o dye.
70545 ..	Mr angiography head w/dye.
70546 ..	Mr angiography head w/o & w/dye.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION—Continued

CPT code	Short descriptor
70547 ..	Mr angiography neck w/o dye.
70548 ..	Mr angiography neck w/dye.
70549 ..	Mr angiography neck w/o & w/dye.
70551 ..	Mri brain w/o dye.
70552 ..	Mri brain w/dye.
70553 ..	Mri brain w/o & w/dye.
70554 ..	Fmri brain by tech.
71250 ..	Ct thorax w/o dye.
71260 ..	Ct thorax w/dye.
71270 ..	Ct thorax w/o & w/dye.
71275 ..	Ct angiography, chest.
71550 ..	Mri chest w/o dye.
71551 ..	Mri chest w/dye.
71552 ..	Mri chest w/o & w/dye.
71555 ..	Mri angio chest w/or w/o dye.
72125 ..	CT neck spine w/o dye.
72126 ..	Ct neck spine w/dye.
72127 ..	Ct neck spine w/o & w/dye.
72128 ..	Ct chest spine w/o dye.
72129 ..	Ct chest spine w/dye.
72130 ..	Ct chest spine w/o & w/dye.
72131 ..	Ct lumbar spine w/o dye.
72132 ..	Ct lumbar spine w/dye.
72133 ..	Ct lumbar spine w/o & w/dye.
72141 ..	Mri neck spine w/o dye.
72142 ..	Mri neck spine w/dye.
72146 ..	Mri chest spine w/o dye.
72147 ..	Mri chest spine w/dye.
72148 ..	Mri lumbar spine w/o dye.
72149 ..	Mri lumbar spine w/dye.
72156 ..	Mri neck spine w/o & w/dye.
72157 ..	Mri chest spine w/o & w/dye.
72158 ..	Mri lumbar spine w/o & w/dye.
72159 ..	Mr angio spone w/o&w/dye.
72191 ..	Ct angiography, pelv w/o & w/dye.
72192 ..	Ct pelvis w/o dye.
72193 ..	Ct pelvis w/dye.
72194 ..	Ct pelvis w/o & w/dye.
72195 ..	Mri pelvis w/o dye.
72196 ..	Mri pelvis w/dye.
72197 ..	Mri pelvis w/o &w/dye.
72198 ..	Mri angio pelvis w/or w/o dye.
73200 ..	Ct upper extremity w/o dye.
73201 ..	Ct upper extremity w/dye.
73202 ..	Ct upper extremity w/o & w/dye.
73206 ..	Ct angio upper extr w/o & w/dye.
73218 ..	Mri upper extr w/o dye.
73219 ..	Mri upper extr w/dye.
73220 ..	Mri upper extremity w/o & w/dye.
73221 ..	Mri joint upper extr w/o dye.
73222 ..	Mri joint upper extr w/dye.
73223 ..	Mri joint upper extr w/o & w/dye.
73225 ..	Mr angio upr extr w/o&w/dye.
73700 ..	Ct lower extremity w/o dye.
73701 ..	Ct lower extremity w/dye.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION—Continued

CPT code	Short descriptor
73702 ..	Ct lower extremity w/o & w/dye.
73706 ..	Ct angio lower ext w/o & w/dye.
73718 ..	Mri lower extremity w/o dye.
73719 ..	Mri lower extremity w/dye.
73720 ..	Mri lower ext w/& w/o dye.
73721 ..	Mri joint of lwr extre w/o dye.
73722 ..	Mri joint of lwr extr w/dye.
73723 ..	Mri joint of lwr extr w/o & w/dye.
73725 ..	Mr angio lower ext w or w/o dye.
74150 ..	Ct abdomen w/o dye.
74160 ..	Ct abdomen w/dye.
74170 ..	Ct abdomen w/o & w/dye.
74174 ..	Ct angiography, abdomen and pelvis w/o & w/dye.
74175 ..	Ct angiography, abdom w/o & w/dye.
74176 ..	Ct abdomen and pelvis w/o dye.
74177 ..	Ct abdomen and pelvis w/dye.
74178 ..	Ct abdomen and pelvis w/and w/o dye.
74181 ..	Mri abdomen w/o dye.
74182 ..	Mri abdomen w/dye.
74183 ..	Mri abdomen w/o and w/dye.
74185 ..	Mri angio, abdom w/or w/o dye.
74261 ..	Ct colonography, w/o dye.
74262 ..	Ct colonography, w/dye.
75557 ..	Cardiac mri for morph.
75559 ..	Cardiac mri w/stress img.
75561 ..	Cardiac mri for morph w/dye.
75563 ..	Cardiac mri w/stress img & dye.
75565 ..	Card mri vel flw map add-on.
75571 ..	Ct hrt w/o dye w/ca test.

TABLE 3—CPT CODES SUBJECT TO 90 PERCENT EQUIPMENT UTILIZATION RATE ASSUMPTION—Continued

CPT code	Short descriptor
75572 ..	Ct hrt w/3d image.
75573 ..	Ct hrt w/3d image, congen.
75574 ..	Ct angio hrt w/3d image.
75635 ..	Ct angio abdominal arteries.
76380 ..	CAT scan follow up study.
77058 ..	Mri, one breast.
77059 ..	Mri, broth breasts.
77078 ..	Ct bone density, axial.
77084 ..	Magnetic image, bone marrow.

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 4. See 77 FR 68902 for a thorough discussion of this issue.

TABLE 4—SBA MAXIMUM INTEREST RATES

Price	Useful life	Interest rate (percent)
<$25K	<7 Years	7.50

TABLE 4—SBA MAXIMUM INTEREST RATES—Continued

Price	Useful life	Interest rate (percent)
$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

See 77 FR 68902 for a thorough discussion of this issue.

TABLE 5—CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est non-facility	33533 CABG, arterial, single facility	71020 Chest x-ray non-facility	71020–TC Chest x-ray non-facility	71020–26 Chest x-ray non-facility	93000 ECG, complete non-facility	93005 ECG, tracing non-facility	93010 ECG, report non-facility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	0.00	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	7.24	7.24	0.00	0.11	0.11	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	78.10	16.38	16.38	0.00	7.42	7.42	0.00
(5) Direct adjustment (Dir. Adj.).	Steps 2–4	See footnote*		0.5427	0.5427	0.5427	0.5427	0.5427	0.5427	0.5427	0.5427
(6) Adjusted Labor	Steps 2–4	=Labor * Dir Adj	=(1)*(5)	7.23	42.07	3.11	3.11	0.00	3.32	3.32	0.00
(7) Adjusted Supplies	Steps 2–4	=Eqp * Dir Adj	=(2)*(5)	1.62	0.00	1.84	1.84	0.00	0.65	0.65	0.00
(8) Adjusted Equipment	Steps 2–4	=Sup * Dir Adj	=(3)*(5)	0.09	0.32	3.93	3.93	0.00	0.06	0.06	0.00
(9) Adjusted Direct	Steps 2–4		=(6)+(7)+(8)	8.94	42.39	8.89	8.89	0.00	4.03	4.03	0.00
(10) Conversion Factor (CF)	Step 5	PFS		34.0230	34.0230	34.0230	34.0230	34.0230	34.0230	34.0230	34.0230
(11) Adj. labor cost converted.	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.21	1.24	0.09	0.09	0.00	0.10	0.10	0.00
(12) Adj. supply cost converted.	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.00	0.05	0.05	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	0.12	0.12	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted.	Step 5		=(11)+(12)+(13)	0.26	1.25	0.26	0.26	0.00	0.12	0.12	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		0.31	0.18	0.31	0.31	0.31	0.31	0.31	0.31
(17) Ind_pct	Steps 6,7	Surveys		0.69	0.82	0.69	0.69	0.69	0.69	0.69	0.69
(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	0.79	5.87	0.64	0.64	0.00	0.29	0.29	0.00
(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	0.27	0.10	0.17
(22) Indirect Allocator (1st + 2nd).	Step 8		=(19)+(21)	1.76	39.62	0.95	0.73	0.22	0.56	0.39	0.17
(23) Indirect Adjustment (Ind. Adj.).	Steps 9–11	See Footnote**		0.3826	0.3826	0.3826	0.3826	0.3826	0.3826	0.3826	0.3826
(24) Adjusted Indirect Allocator.	Steps 9–11	=Ind Alloc * Ind Adj		0.67	15.16	0.36	0.28	0.08	0.21	0.15	0.07
(25) Ind. Practice Cost Index (IPCI).	Steps 12–16			1.08	0.77	0.93	0.93	0.93	0.91	0.91	0.91
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24)*(25)	0.73	11.60	0.34	0.26	0.08	0.19	0.14	0.06
(27) Pre-Cap PE RVU	Step 18	=(Adj Dir + Adj Ind) * Other Adj.	=((14)+(26)) * Other Adj)***	0.98	12.78	0.61	0.53	0.08	0.32	0.26	0.06
(28) OPPS/ASC Cap Adj	Step 19	PFS		1.016	1.016	1.016	1.016	1.016	1.016	1.016	1.016
(29) Final PE RVU	Step 19	PE RVU * OPPS/ASC Cap Adj.	(27)*(28)	1.00	12.99	0.62	0.54	0.08	0.32	0.26	0.06

Note: PE RVUs in Table 5, row 28, may not match Addendum B due to rounding.

*The direct adj = [current PE RVUs * CF * avg dir pct]/[sum direct inputs] = [Step 2]/[Step 3]

**The indirect adj = [current PE RVUs * avg ind pct]/[sum of ind allocators] = [Step 9]/[Step 10]

***The other adjustment includes adjustments for the changes in the equipment utilization rate for certain services and the MEI revisions.

Note: The use of any particular conversion factor (CF) in Table 5 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 2014 proposals and revisions related to direct PE inputs for specific services. The proposed revisions are included in the proposed rule CY 2014 direct PE database, which is available on the CMS Web site under the supporting data files for the CY 2014 PFS proposed rule with comment period at *www.cms.gov/PhysicianFeeSched/.*

a. Anomalous Supply Inputs

In the CY 2013 PFS final rule with comment period, we established interim final direct PE inputs based on acceptance, with refinement, of recommendations submitted by the AMA RUC. Although we generally address public comments on the prior year's interim final direct PE inputs in the following year's final rule with comment period, several commenters raised an issue regarding anomalous supply items that we believe is best addressed through proposed revisions to the direct PE inputs.

For the CY 2013 interim final direct PE inputs for a series of codes that describe six levels of surgical pathology services (CPT codes 88300, 88302, 88304, 88305, 88307, 88309), we did not accept the AMA RUC recommendation to create two new direct PE supply inputs because we did not consider these items to be disposable supplies (77 FR 69074). The recommended new items were called ''specimen, solvent, and formalin disposal cost,'' and ''courier transportation costs.'' In the CY 2013 PFS final rule with comment period, we explained that neither the specimen and supply disposal nor courier costs for transporting specimens are appropriately considered disposable medical supplies. Instead, we stated these costs are incorporated into the PE RVUs for these services through the indirect PE allocation. We also noted that the current direct PE inputs for these and similar services across the PFS do not include these kinds of costs as disposable supplies.

Several commenters noted that, contrary to our assertion in the final rule with comment period, there are a few items incorporated in the direct PE input database as ''supplies'' that are no more disposable supplies than the new items recommended by the AMA RUC for the surgical pathology codes. These commenters identified seven supply inputs in particular that they believe are analogous to the items that we did not accept in establishing CY 2013 interim final direct PE inputs. These items and their associated HCPCS codes are listed in Table 6.

TABLE 6—ITEMS IDENTIFIED BY COMMENTERS

CMS supply code	Item description	Associated CPT codes
SK106	device shipping cost	93271, 93229, 93268.
SK112	Federal Express cost (average across all zones)	64650, 88363, 64653.
SK113	communication, wireless per service	93229.
SK107	fee, usage, cycletron/accelerator, gammaknife, Lincac SRS System.	77423, 77422.
SK110	fee, image analysis	96102, 96101, 99174.
SK111	fee, licensing, computer, psychology	96102, 96101, 96103, 96120.
SD140	bag system, 1000ml (for angiography waste fluids)	93451, 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461.

We reviewed each of these items for consistency with the general principles of the PE methodology regarding the consistent categorization of all costs. Within the PE methodology, all costs other than clinical labor, disposable supplies, and medical equipment are considered indirect costs. For six of the items contained in Table 6, we agree with the commenters that the items should not be considered disposable supplies. We believe that these items are more appropriately categorized as indirect PE costs, which are reflected in the allocation of indirect PE RVUs rather than direct PE. Therefore, we are proposing to remove the following six items from the direct PE input database for CY 2014: ''device shipping cost'' (SK106); ''Federal Express cost (average across all zones)'' (SK112); ''communication, wireless per service'' (SK113); ''fee, usage, cycletron/accelerator, gammaknife, Lincac SRS System'' (SK107); ''fee, image analysis'' (SK110); and ''fee, licensing, computer, psychology'' (SK111). The CY 2014 proposed direct PE input database and Addendum B of this proposed rule reflect these proposed revisions.

In the case of the supply item called ''bag system, 1000ml (for angiography waste fluids)'' (SD140), we do not agree with the commenters that this item is analogous to the specimen disposal costs recommended for the surgical pathology codes. This supply input represents only the costs of the disposable material items associated with the removal of waste fluids that typically result from a particular procedure. In contrast, the item recommended by the AMA RUC for surgical pathology consisted of an amortized portion of a specimen disposal contract that includes costs for resources such as labor and transportation. Furthermore, we do not believe that the specimen disposal contract is attributable to individual procedures within the established PE methodology. We believe that a disposable supply is one that is attributable, in its entirety, to an individual patient for a particular service. An amortized portion of a specimen disposal contract does not meet these criteria. Accordingly, as stated in the CY 2013 final rule with comment period, we did not accept the AMA RUC recommendation to create a new supply item related to specimen disposal costs. We believe that many physician offices and other nonfacility settings where Medicare beneficiaries receive services incur costs related to waste management or other service contracts, but none of these costs are currently incorporated into the PE methodology as disposable supplies. Instead, these costs are appropriately categorized as indirect costs and are reflected in the PE RVUs through the allocation of indirect PE. We are clarifying that we believe that supply costs related to specimen disposal attributable to individual services may be appropriately categorized as disposable supplies, but that specimen disposal costs related to an allocated portion of service contracts that cannot be attributed to individual services should not be incorporated into the direct PE input database as disposable supplies.

Moreover, because do not agree with commenters that the ''bag system, 1000ml (for angiography waste fluids)'' (SD140) is analogous to a specimen disposal contract for the reasons state above, we continue to believe that SD140 is a direct expense. Accordingly, we are not removing SD140 from the direct PE input database. Additionally, we anticipate responding to these and other aspects of the comments regarding the direct PE inputs for the surgical pathology services in the CY 2014 PFS final rule with comment period.

b. Direct PE Input Refinements based on Routine Data Review

In reviewing the direct PE input database, we have identified several discrepancies that we believe should be addressed for CY 2014. In the following paragraphs, we identify the nature of these discrepancies, the affected codes, and the refinements displayed in the CY 2014 proposed direct PE input database. As part of our internal review of information in the direct PE input database, we identified supply items that appeared without quantities for CPT code 51710 (Change of cystostomy tube; complicated). Upon reviewing these items we believe that the codes should include the items at the quantities listed in Table 7.

TABLE 7—SUPPLY ITEMS AND QUANTITIES FOR CPT CODE 51710

Supply code	Description of supply item	NF quantity
SA069	tray, suturing	1.0
SB007	drape, sterile barrier 16in x 29in.	1.0
SC029	needle, 18–27g	1.0
SC051	syringe 10–12ml	1.0
SD024	catheter, Foley	1.0
SD088	Guidewire	1.0
SF036	suture, nylon, 3–0 to 6–0, c.	1.0
SG055	gauze, sterile 4in x 4in	1.0
SG079	tape, surgical paper 1in (Micropore).	6.0
SH075	water, sterile inj	3.0
SJ032	lubricating jelly (K–Y) (5gm uou).	1.0

TABLE 7—SUPPLY ITEMS AND QUANTITIES FOR CPT CODE 51710—Continued

Supply code	Description of supply item	NF quantity
SJ041	povidone soln (Betadine)	20.0

Upon reviewing the direct PE inputs for CPT code 51710 and the related code 51705 (Change of cystostomy tube; simple), we also noted that the direct PE input database includes an anomalous 0.5 minutes of clinical labor time in the post-service period. We believe that this small portion of clinical labor time is the result of a rounding error in our data and should be removed from the direct PE input database.

During our review of the data, we noted an invalid supply code (SM037) that appears in the direct PE input database for CPT codes 88312 and 88313. Upon review of the code, we believe that the supply item called ''wipes, lens cleaning (per wipe) (Kimwipe)'' (SM027) should be included in the code instead of the invalid code. The CY 2014 proposed direct PE input database reflects these proposed revisions.

Additionally, we conducted a routine review of the codes valued in the nonfacility setting for which moderate sedation is inherent in the procedure. Consistent with the standard moderate sedation package finalized in the CY 2012 PFS final rule with comment period (76 FR 73043), we have made minor adjustments to the nurse time and equipment time of 18 of these codes. These codes appear in Table 8, and the CY 2014 proposed direct PE input database reflects the proposed refined inputs for moderation sedation.

TABLE 8—CODES WITH MINOR ADJUSTMENTS TO MODERATE SEDATION INPUTS

CPT code	Descriptor
31629	Bronchoscopy/needle bx each.
31645	Bronchoscopy clear airways.
31646	Bronchoscopy reclear airway.
32405	Percut bx lung/mediastinum.
32550	Insert pleural cath.
35471	Repair arterial blockage.
37183	Remove hepatic shunt (tips).
37210	Embolization uterine fibroid.
43453	Dilate esophagus.
43458	Dilate esophagus.
44394	Colonoscopy w/snare.
45340	Sig w/balloon dilation.
47000	Needle biopsy of liver.
47525	Change bile duct catheter.
49411	Ins mark abd/pel for rt perq.
50385	Change stent via transureth.
50386	Remove stent via transureth.
57155	Insert uteri tandem/ovoids.
93312	Echo transesophageal.
93314	Echo transesophageal.
G0341	Percutaneous islet celltrans.

c. Adjustments to Pre-Service Clinical Labor Minutes

We recently received a recommendation from the AMA RUC regarding appropriate pre-service clinical labor minutes in the facility setting for codes with 000 day global periods. In general, the AMA RUC has recommended that codes with 000 day global period include a maximum of 30 minutes of clinical labor time in the pre-service period in the facility setting. The AMA RUC identified 48 codes that currently include more clinical labor time than this recommended maximum and provided us with recommended pre-service clinical labor minutes in the facility setting of 30 minutes or fewer for these 48 codes. We reviewed the AMA RUC's recommendation and agree that the recommended reductions would be appropriate to maintain relativity with other 000 day global codes. Therefore, we propose to amend the pre-service clinical labor minutes for the codes listed in Table 9, consistent with the AMA RUC recommendation. The proposed CY 2014 direct PE input database reflects this proposal.

TABLE 9—000-DAY GLOBAL CODES WITH PROPOSED CHANGES TO PRE-SERVICE CL TIME

CPT code	Short descriptor	Existing CL pre-service facility minutes	Proposed CL pre-service facility minutes (AMA RUC recommendation)
20900	Removal of bone for graft	60	30
20902	Removal of bone for graft	60	30
33224	Insert pacing lead & connect	35	30
33226	Reposition l ventric lead	35	30
36800	Insertion of cannula	60	0
36861	Cannula declotting	37	0
37202	Transcatheter therapy infuse	45	0
50953	Endoscopy of ureter	60	30

TABLE 9—000-DAY GLOBAL CODES WITH PROPOSED CHANGES TO PRE-SERVICE CL TIME—Continued

CPT code	Short descriptor	Existing CL pre-service facility minutes	Proposed CL pre-service facility minutes (AMA RUC recommendation)
50955	Ureter endoscopy & biopsy	60	30
51726	Complex cystometrogram	41	30
51785	Anal/urinary muscle study	34	30
52250	Cystoscopy and radiotracer	37	30
52276	Cystoscopy and treatment	32	30
52277	Cystoscopy and treatment	37	30
52282	Cystoscopy implant stent	31	30
52290	Cystoscopy and treatment	31	30
52300	Cystoscopy and treatment	36	30
52301	Cystoscopy and treatment	36	30
52334	Create passage to kidney	31	30
52341	Cysto w/ureter stricture tx	42	30
52342	Cysto w/up stricture tx	42	30
52343	Cysto w/renal stricture tx	42	30
52344	Cysto/uretero stricture tx	55	30
52345	Cysto/uretero w/up stricture	55	30
52346	Cystouretero w/renal strict	55	30
52351	Cystouretero & or pyeloscope	45	30
52352	Cystouretero w/stone remove	50	30
52353	Cystouretero w/lithotripsy	50	30
52354	Cystouretero w/biopsy	50	30
52355	Cystouretero w/excise tumor	50	30
54100	Biopsy of penis	33	30
61000	Remove cranial cavity fluid	60	15
61001	Remove cranial cavity fluid	60	15
61020	Remove brain cavity fluid	60	15
61026	Injection into brain canal	60	15
61050	Remove brain canal fluid	60	15
61055	Injection into brain canal	60	15
61070	Brain canal shunt procedure	60	15
62268	Drain spinal cord cyst	36	30
67346	Biopsy eye muscle	42	30
68100	Biopsy of eyelid lining	32	30
93530	Rt heart cath congenital	35	30
93531	R & l heart cath congenital	35	30
93532	R & l heart cath congenital	35	30
93533	R & l heart cath congenital	35	30
93580	Transcath closure of asd	35	30
93581	Transcath closure of vsd	35	30

d. Price Adjustment for Laser Diode

It has come to our attention that the price associated with the equipment item called ''laser, diode, for patient positioning (Probe)'' (ER040) in the direct PE input database is $7,678 instead of $18,160 as listed in the CY 2013 PFS final rule with comment period (77 FR 68922). The CY 2014 proposed direct PE input database reflects the updated price for the equipment item.

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

Since 2001, Medicare has used HCPCS G-codes, in addition to the CPT codes, for stereotactic radiosurgery (SRS) to distinguish robotic and non-robotic methods of delivery. Based on our review of the current SRS technology, it is our understanding that most services currently furnished with linac-based SRS technology, including services currently billed using the non-robotic codes, incorporate some type of robotic feature. Therefore, we believe that it is no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through the HCPCS G-codes. For purposes of the hospital outpatient prospective payment system (OPPS), CMS is proposing to replace the existing four SRS HCPCS G-codes G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session), G0251 (Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment), 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), with the SRS CPT codes 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) that do not distinguish between robotic and non-robotic methods of delivery. We refer readers to section II.C.3 of the CY 2014 OPPS proposed rule for more discussion of that proposal. We also refer readers to the CY 2007 OPPS final rule (71 FR 68023 through 68026) for a

detailed discussion of the history of the SRS codes.

Two of the four current SRS G-codes are paid in the nonfacility setting through the PFS. These two codes, G0339 and G0340, describe robotic SRS treatment delivery and are contractor-priced. CPT codes 77372 and 77373, which describe SRS treatment delivery without regard to the method of delivery, are currently paid in the nonfacility setting based on resource-based RVUs developed through the standard PE methodology. If the CY 2014 OPPS proposal is implemented, it would appear that there would no longer be a need for G-codes to describe robotic SRS treatment and delivery. Prior to eliminating the contractor-priced G-codes and using the existing CPT code for PFS payment of services previously reported using G-codes, we believe that it would be appropriate to ensure that the direct PE inputs used to develop PE RVUs for CPT codes 77372 and 77373 accurately reflect the typical resources used in furnishing the services that would be reported in the non-facility setting in the absence of the robotic G-codes. Therefore, for CY 2014, we are not proposing to replace the contractor-priced G-codes for PFS payment. We are seeking comment from the public and stakeholders, including the AMA RUC, regarding whether or not the direct PE inputs for CPT codes 77372 and 77373 would continue to accurately estimate the resources used in furnishing typical SRS delivery were there no coding distinction between robotic and non-robotic methods of delivery.

3. Using OPPS and ASC Rates in Developing PE RVUs

As we explain in section II.A.2.d of this proposed rule, we typically establish two PE RVUs for procedures that can be furnished in either a nonfacility setting, like a physician's office, or facility setting, like a hospital. The nonfacility RVUs reflect all of the direct and indirect practice expenses of providing a particular service when the entire service is furnished in a nonfacility setting. The facility RVUs are designed to reflect the direct and indirect practice expenses typically associated with furnishing a particular service in a setting, such as a hospital or ASC where those facilities incur a portion or all of the costs. Thus, the difference between the facility and nonfacility RVUs is because Medicare makes a separate payment to the facility for its costs of furnishing a service when a service is furnished in a facility.

When services are furnished in the facility setting, such as a hospital outpatient department (OPD) or an ambulatory surgical center (ASC), the total Medicare payment (made to the facility and the professional combined) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting. We believe that this payment difference generally reflects the greater costs that facilities incur than those incurred by practitioners furnishing services in offices and other non-facility settings. For example, hospitals incur higher overhead costs because they maintain the capability to furnish services 24 hours a day and 7 days per week, furnish services to higher acuity patients than those who receive services in physician offices, and have additional legal obligations such as complying with the Emergency Medical Treatment and Active Labor Act (EMTALA). Additionally, hospitals and ASCs must meet Medicare conditions of participation and conditions for coverage, respectively.

However, we have found that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in an OPD or an ASC. When this occurs, we believe it is not the result of appropriate payment differentials between the services furnished in different settings. Rather, we believe it is due to anomalies in the data we use under the PFS and in the application of our resource-based PE methodology to the particular services.

The PFS PE RVUs rely heavily on the voluntary submission of information by individuals furnishing the service and who are paid at least in part based on the data provided. Currently, we have little means to validate whether the information is accurate or reflects typical resource costs. Furthermore, in the case of certain direct costs, like the price of high-cost disposable supplies and expensive capital equipment, even voluntary information has been very difficult to obtain. In some cases the PE RVUs are based upon single price quotes or one paid invoice. We have addressed these issues extensively in previous rulemaking (75 FR 73252) and again in section II.A.3.e of this proposed rule. Such incomplete, small sample, potentially biased or inaccurate resource input costs may distort the resources used to develop nonfacility PE RVUs used in calculating PFS payment rates for individual services.

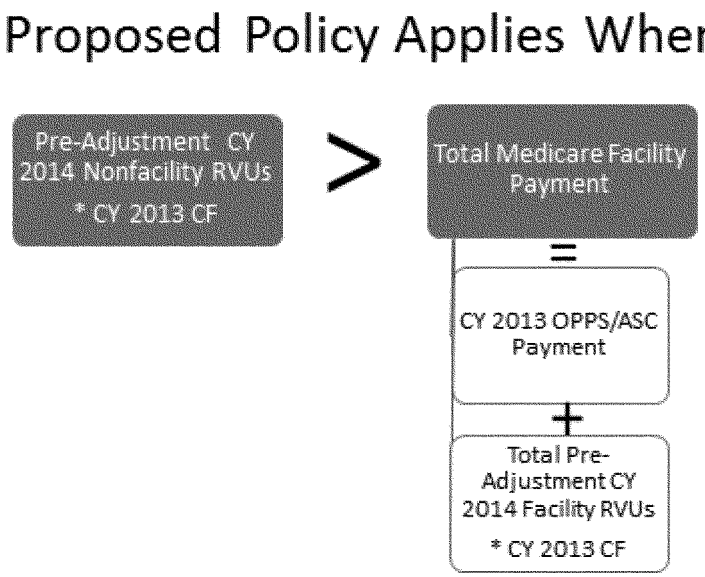
In addition to the accuracy issues with some of the physician PE resource inputs, the data used in the PFS PE methodology can often be outdated. As we have previously noted (77 FR 68921) there is no practical means for CMS or stakeholders to engage in a complete simultaneous review of the input resource costs for all HCPCS codes paid under the PFS on an annual or even regular basis. Thus, the information used to estimate PE resource costs for PFS services is not routinely updated. Instead, we strive to maintain relativity by reviewing the work RVUs, physician time, and direct PE inputs for a code at the same time and reviewing all codes within families where appropriate. Nonetheless, outdated resource input costs may distort RVUs used to develop nonfacility PFS payment rates for individual services. In the case of new medical devices for which high growth in volume of a service as it diffuses into clinical practice may lead to a decrease in the cost of expensive items, outdated price inputs can result in significant overestimation of resource costs.

Such inaccurate resource input costs may distort the nonfacility PE RVUs used to calculate PFS payment rates for individual services. As we have previously noted, OPPS payment rates are based on auditable hospital data and are updated annually. Given the differences in the validity of the data used to calculate payments under the PFS and OPPS, we believe that the nonfacility PFS payment rates for procedures that exceed those for the same procedure when in a facility result from inadequate or inaccurate direct PE inputs, especially in price or time assumptions, as compared to the more accurate OPPS data. On these bases, we are proposing a change in the PE methodology beginning in CY 2014 and subsequent years. To improve the accuracy of PFS nonfacility payment rates for each calendar year, we are proposing to use the current year OPPS or ASC rates as a point of comparison in establishing PE RVUs for services under the PFS. In setting PFS rates, we would compare the PFS payment rate for a service furnished in an office setting to the total Medicare payment to practitioners and facilities for the same service when furnished in a hospital outpatient setting. For services on the ASC list, we would make the same comparison except we would use the ASC rate as the point of comparison instead of the OPPS rate.

We are proposing to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount Medicare would pay for the same code in the facility setting. That is, if the nonfacility PE RVUs for a code would result in a higher payment than the corresponding

OPPS or ASC payment rate and PFS facility PE RVUs (when applicable) for the same code, we would reduce the nonfacility PE RVU rate so that the total nonfacility payment does not exceed the total Medicare payment made for the service in the facility setting. To maintain the greatest consistency and transparency possible, we are proposing to use the current year PFS conversion factor, as reflected in Figure B1. Similarly, we are proposing to use current year OPPS or ASC rates in the comparison.

Figure B1



For services with no work RVUs, we are proposing to compare the total nonfacility PFS payment to the OPPS payment rates directly since no PFS payment is made for these services when furnished in the facility setting.

We are proposing to exempt the following services from this policy:

Services Without Separate OPPS Payment rates: We are proposing to exclude services without separately payable OPPS rates from this methodical change since there would be no OPPS rate to which we could compare the PFS nonfacility PE RVUs. We note that there would also be no ASC rate for these services since ASCs are only approved to furnish a subset of OPPS services.

Codes Subject to the DRA Imaging Cap: We are proposing to exclude services capped at the OPPS payment rate by the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) from this policy. The DRA provision limits PFS payment for most imaging procedures to the amount paid under the OPPS system. This policy applies to the technical component of imaging services, including X-ray, ultrasound, nuclear medicine, MRI, CT, and fluoroscopy services. Screening and diagnostic mammograms are exempt. Since payment for these procedures is capped by statute we are excluding them from this policy.

Codes with Low Volume in the OPPS or ASC: We are proposing to exclude any service for which 5% percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services.

Codes with ASC Rates Based on PFS Payment Rates: To avoid issues of circularity, we are proposing to exclude ASC services subject to the ''office-based'' procedure payment policies for which payment rates are based on the PFS nonfacility PE RVUs. We direct interested readers to the CY 2013 OPPS final rule (77 FR 68444) for additional information regarding this payment policy.

Codes Paid in the Facility at Nonfacility PFS Rates: To avoid issues of circularity, we are also proposing to exclude services that are paid in the facility setting at nonfacility payment rates. This would include certain professional-only services where the resource costs for practitioners are assumed to be similar in both settings.

Codes with PE RVUs Developed Outside the PE Methodology: We are also proposing to exclude services with PE RVUs established outside the PE Methodology through notice and comment rulemaking.

Addendum B of this proposed rule with comment period displays the PE RVUs that would result from implementation of this proposed change in the PE methodology.

In discussing resource input issues, some stakeholders have previously suggested that the direct costs (for example, clinical labor, disposable supplies and medical equipment) involved in furnishing a service are similar in both the nonfacility and facility settings. Others have suggested that facilities, like hospitals, have greater purchasing power for medical equipment and disposable supplies so that the direct costs for a facility to furnish a service can be lower than costs for a physician practice furnishing the same service. This proposed policy does not assume that the direct costs to furnish a service in the nonfacility setting are always lower than in the facility setting. Medicare payment methodologies, including both OPPS and the PFS PE methodology, incorporate both direct and indirect costs (administrative labor, office expenses, and all other expenses). This proposed policy is premised on the idea that there are significantly greater indirect resource costs that are carried by facilities even in the event that the direct costs involved in furnishing a service in the office and facility settings are comparable.

We believe this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures based on relatively more

reliable cost information available for the same procedures when furnished in a facility setting where the cost structure would be expected to be somewhat, if not significantly, higher than the office setting. We believe that the current basis for estimating the resource costs involved in furnishing a PFS service is significantly encumbered by our current inability to obtain accurate information regarding supply and equipment prices, as well as procedure time assumptions. We believe that this policy will mitigate the negative impact of these difficulties on both the appropriate relativity of PFS services and overall Medicare spending. A wide range of stakeholders and public commenters have pointed to the nonfacility setting as the most cost-effective location for services. Given the significantly higher cost structure of facilities (as discussed above) we believe that this presumption is accurate. In its March 2012 report to Congress, MedPAC recommended that Medicare should seek to pay similar amounts for similar services across payment settings, taking into account differences in the definitions of services and patient severity. (MedPAC March 2012 Report to Congress, page 46) We believe that the proposed change to our PFS PE methodology will more appropriately reflect resource costs in the nonfacility setting.

b. Ultrasound Equipment Recommendations

In the CY 2012 PFS proposed rule (76 FR 42796), we asked the AMA RUC to review the ultrasound equipment described in the direct PE input database. We specifically asked for review of the ultrasound equipment items described in the direct PE input database and whether the ultrasound equipment listed for specific procedure codes is clinically necessary.

In response, the AMA RUC recommended creating several new equipment inputs in addition to the revision of current equipment inputs for ultrasound services. The AMA RUC also forwarded pricing information for new and existing equipment items from certain medical specialty societies that represent the practitioners who furnish these services. In the following paragraphs, we summarize the AMA RUC recommendations, address our review of the provided information, and describe proposed changes to the direct PE inputs used in developing PE RVUs for these services.

(1) Equipment Rooms

The AMA RUC made a series of recommendations regarding the ultrasound equipment items included in direct PE input equipment packages called ''rooms.'' Specifically, the AMA RUC recommended adding several new equipment items to the equipment packages called ''room, ultrasound, general'' (EL015) and ''room, ultrasound, vascular'' (EL016). The AMA RUC also recommended creating a similar direct PE input equipment package called ''room, ultrasound, cardiovascular.'' In considering these recommendations, we identified a series of new concerns regarding the makeup of these equipment packages and because there are several different ways to handle these concerns, we are seeking public comment from additional stakeholders prior to proposing to implement any of these recommended changes through future rulemaking.

We note that the existing ''rooms'' for ultrasound technology include a greater number of individual items than the ''rooms'' for other kinds of procedures. For example, the equipment package for the ''room, basic radiology'' (EL012) contains only two items: An x-ray machine and a camera. Ordinarily under the PFS, direct PE input packages for ''rooms'' include only equipment items that are typically used in furnishing every service in that room. When equipment items beyond those included in a ''room'' are typically used in furnishing a particular procedure, the additional equipment items for that procedure are separately reflected in the direct PE input database in addition to the ''room'' rather than being included in the room. When handled in this way, the room includes only those inputs that are common to all services furnished in that room type, and thus the direct PE inputs are appropriate for the typical case of each particular service. When additional equipment items are involved in furnishing a particular service, they are included as an individual PE input only for that particular service.

In contrast, the equipment items currently included in the ''room, ultrasound, general'' are: the ultrasound system, five different transducers, two probe starter kits, two printers, a table, and various other items. We do not believe that it is likely that all of these items would be typically used in furnishing each service. For example, we do not believe that the typical ultrasound study would require the use of five different ultrasound transducers. However, the costs of all of these items are incorporated into the resource inputs for every service for which the ultrasound room is a direct PE input, regardless of whether each of those items is typically used in furnishing the particular service. This increases the resource cost for every service that uses the room regardless of whether or not each of the individual items is typically used in furnishing a particular procedure.

Instead of incorporating the AMA RUC's recommendation to add more equipment items to these ultrasound equipment ''room'' packages, we believe that we should continue to consider the appropriateness of the full number of items in the ultrasound ''rooms'' in the context of maintaining appropriate relativity with other services across the PFS. We seek comment from stakeholders, including the AMA RUC, on the items included in the ultrasound rooms, especially as compared to the items included in other equipment ''rooms.'' We believe that it would be appropriate to consider these comments in future rulemaking. Specifically we seek comment on whether equipment packages called ''rooms'' should include all of the items that might be included in an actual room, just the items typically used for every service in such a room, or all of the items typically used in typical services furnished in the room. We believe that it would be most appropriate to propose changes to the ''room, ultrasound, general'' (EL015) and ''room, ultrasound, vascular'' (EL016) in the context of considering comments on this broader issue. We also believe that consideration of the broader issue will help determine whether it would be appropriate to create a ''room, ultrasound, cardiovascular,'' and if so, what items would be included in this equipment package.

In addition to the concerns regarding the contents of the ultrasound ''room'' packages, we are also concerned about the pricing information submitted through the AMA RUC to support its recommendation to add equipment to the ultrasound room packages. The highest-price item used in pricing the existing equipment input called ''room, ultrasound, general'' (EL015), is a ''GE Logic 9 ultrasound system,'' currently priced at $220,000. As part of a current AMA RUC recommendation, a medical specialty society recommended increasing the price of that item to $314,500. However, that recommendation did not include documentation to support the pricing level, such as a copy of a paid invoice for the equipment. Furthermore, the recommended price conflicts with certain publicly available information. For example, the *Milwaukee Sentinel-Journal* reported in a February 9, 2013 article that the price for GE ultrasound equipment ranges from ''$7,900 for a hand-held ultrasound to $200,000 for its

most advanced model.'' The same article points to an item called the ''Logiq E9'' as the ultrasound machine most used by radiologists and priced from $150,000 to $200,000. *http://www.jsonline.com/business/ge-sees-strong-future-with-its-ultrasound-business-uj8mn79-190533061.html*

At this time, are unsure how to best reconcile the information disclosed by the manufacturer to the press and the prices submitted by the medical specialty society for use in updating the direct PE input prices. We believe discrepancies, such as these, exemplify the potential problem with updating prices for particular items based solely on price quotes or information other than copies of paid invoices. However, copies of paid invoices must also be evaluated carefully. The information presented in the article regarding the price for hand-held ultrasound devices raises questions about the adequacy of paid invoices, too, in determining appropriate input costs. The direct PE input described in the database as ''ultrasound unit, portable'' (EQ250) is currently priced at $29,999 based on a submitted invoice, while the article cites that GE sells a portable unit for as low as $7,900. We are seeking comment on the appropriate price to use as the typical cost for portable ultrasound units.

Additionally, we are not proposing to revise the equipment items, or to change the prices of items, included in these rooms. Instead, pending our receipt and consideration of additional information, the proposed direct PE input database continues to include the current prices for the ''room, ultrasound, general'' (EL015), ''room, ultrasound, vascular'' (EL016), and ''ultrasound unit, portable'' (EQ250).

(2) New Equipment Inputs and Price Updates

Ultrasound Unit, portable, breast procedures. The AMA RUC recommended that a new direct PE input, ''ultrasound unit, portable, breast procedures,'' be created for breast procedures that are performed in a surgeon's office and where ultrasound imaging is included in the code descriptor. These services are described by CPT codes 19105 (Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma), 19296 (Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy), and 19298 (Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance). We are creating this input. The pricing information submitted for this item is a paid invoice and two price quotes. As we have previously stated, we believe that copies of paid invoices are more likely to reflect actual resource costs associated with equipment and supply items than quotes or other information. Therefore, we are proposing a price of $33,930, which reflects the price displayed on the submitted copy of the paid invoice. We are not using the quotes as we do not believe that quotes provide reliable information about the prices that are actually paid for medical equipment.

Endoscopic Ultrasound Processor. The AMA RUC recommended creating a new direct PE input called ''endoscopic ultrasound processor,'' for use in furnishing the service described by CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])). We are creating this equipment item to use as an input in the proposed direct PE input database. The price associated with the ''endoscopic ultrasound processor'' will be $59,925, which reflects the price documented on the copy of the paid invoice submitted with the recommendation.

Bronchofibervideoscope. The AMA RUC recommended creating a new direct PE input called ''Bronchofibervideoscope,'' for use in furnishing the service described by CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])). We are creating this new equipment item to use as an input in the proposed direct PE input database. However, this item has no price associated with it in the proposed direct PE input database because we did not receive any information that would allow us to price the item accurately. Consequently, we seek copies of paid invoices for this equipment item so that we can price the item accurately in the future.

Endoscope, ultrasound probe, drive (ES015). The AMA RUC forwarded pricing information to us regarding the existing input called ''endoscope, ultrasound probe, drive'' (ES015). This information included a copy of a paid invoice. Based on this information, we are proposing to change the price associated with ES015 to $13,256.25, which reflects the price documented on the submitted copy of the paid invoice.

(3) Ultrasound Equipment Input Recommendations for Particular Services

The AMA RUC made recommendations regarding the typical ultrasound items used in furnishing particular services. In general, the AMA RUC recommended that the existing equipment items accurately described the typical equipment used in furnishing particular services. However, for some CPT codes the AMA RUC recommended changing the associated equipment inputs that appear in the direct PE input database. Based on our review of these recommendations, we have generally agreed with the AMA RUC regarding these recommended changes, and these changes are reflected in the proposed direct PE input database. Table 10 displays the codes with proposed changes to ultrasound equipment. However, for certain codes we do not agree with the recommendations of the AMA RUC. The following paragraphs address the changes we are proposing that differ from the recommendations of the AMA RUC.

For a series of cardiovascular services that include ultrasound technology, the AMA RUC recommended removing certain equipment items and replacing those items with a new item called ''room, ultrasound, cardiovascular.'' As we described in the preceding paragraphs, we are not proposing to create the ''room, ultrasound, cardiovascular'' and therefore will not propose to add this ''room'' an input for these services. However, we note that the newly recommended equipment package incorporates many of the same kinds of items as the currently existing ''room, ultrasound, vascular'' (EL016). We agree with the AMA RUC's suggestion that the existing equipment inputs for the relevant services listed in Table 10 do not reflect typical resource costs of furnishing the services. We believe that, pending our further consideration of the ultrasound ''room'' equipment packages, it would be appropriate to use the existing ''room, ultrasound, vascular'' (EL016) as a proxy for resource costs for these services. Therefore, the proposed direct PE input database reflects this proposed change.

In the case of CPT code 76942 (Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation), we agree with the AMA RUC's

recommendation to replace the current equipment input of the ''room, ultrasound, general'' (EL015) with ''ultrasound unit, portable'' (EQ250). We note that this service is typically reported with other codes that describe the needle placement procedures and that the recommended change in equipment from a room to a portable device reflects a change in the typical kinds of procedures reported with this image guidance service. Given this change, we believe that it is appropriate to reconsider the procedure time assumption currently used in establishing the direct PE inputs for this code is 45 minutes, which we believe is inaccurate. We reviewed the services reported with CPT code 76942 to identify the most common procedures furnished with this image guidance. The code most frequently reported with CPT code 76942 is CPT 20610 (Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa). The assumed procedure time for this service is five minutes. The vast majority of other procedures frequently reported with CPT code 76942 range in procedure time assumptions from 5 to 20 minutes. Therefore, in addition to proposing the recommended change in equipment inputs associated with the code, we are also proposing to change the procedure time assumption used in establishing direct PE inputs for the service from 45 to 10 minutes, based on our analysis of thirty needle placement procedures most frequently reported with CPT code 76942. We note that this will reduce the clinical labor and equipment minutes associated with the code from 58 to 23 minutes. This change is reflected in the proposed direct PE input database. We also note that this code has been proposed as a potentially misvalued code in section II.B.3.b.1.

TABLE 10—CODES WITH PROPOSED CHANGES TO ULTRASOUND EQUIPMENT FOR CY 2014

CPT code	Descriptor	CY 2013 CMS Equipment code	CY 2013 Equipment description	Proposed CY 2014 Equipment CMS code	Proposed CY 2014 Equipment description
19105	Cryosurg ablate fa each	EQ250	ultrasound unit, portable	NEW	ultrasound unit, portable, breast procedures.
19296	Place po breast cath for rad	EL015	room, ultrasound, general	NEW	ultrasound unit, portable, breast procedures.
19298	Place breast rad tube/caths	EL015	room, ultrasound, general	NEW	ultrasound unit, portable, breast procedures.
31620	Endobronchial us add-on	n/a		NEW	Bronchofibervideoscope.
		n/a		NEW	Endoscopic ultrasound processor.
52649	Prostate laser enucleation	EQ255	ultrasound, noninvasive bladder scanner w-cart.	EQ250	ultrasound unit, portable.
76376	3d render w/o postprocess	EL015	room, ultrasound, general	Remove input.	
76775	Us exam abdo back wall lim	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76820	Umbilical artery echo	EQ249	ultrasound color doppler, transducers and vaginal probe.	EL015	room, ultrasound, general.
76857	Us exam pelvic limited	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76870	Us exam scrotum	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76872	Us transrectal	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
76942	Echo guide for biopsy	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable.
93303	Echo guide for biopsy	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).	EL016	room, ultrasound, vascular.
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
93304	Echo transthoracic	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93306	Tte w/doppler complete	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).	EL016	room, ultrasound, vascular.
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
93307	Tte w/o doppler complete	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		

TABLE 10—CODES WITH PROPOSED CHANGES TO ULTRASOUND EQUIPMENT FOR CY 2014—Continued

CPT code	Descriptor	CY 2013 CMS Equipment code	CY 2013 Equipment description	Proposed CY 2014 Equipment CMS code	Proposed CY 2014 Equipment description
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93308	Tte f-up or lmtd	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93312	Echo transesophageal	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).	EL016	room, ultrasound, vascular.
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
		EQ256	ultrasound, transducer (TEE Omniplane II).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93314	Echo transesophageal	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).	EL016	room, ultrasound, vascular.
		EQ256	ultrasound, transducer (TEE Omniplane II).		
		EQ252	ultrasound, echocardiography analyzer software (ProSolv).		
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
93320	Doppler echo exam heart	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93321	Doppler echo exam heart	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93325	Doppler color flow add-on	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93350	Stress tte only	EQ252	ultrasound, echocardiography analyzer software (ProSolv).	EL016	room, ultrasound, vascular.
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec).		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).		
93351	Stress tte complete	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256).	EL016	room, ultrasound, vascular.
93980	Penile vascular study	EL015	room, ultrasound, general	EQ249	ultrasound color doppler, transducers and vaginal probe.
93981	Penile vascular study	EL015	room, ultrasound, general	EQ249	ultrasound color doppler, transducers and vaginal probe.

4. Collecting Data on Services Furnished in Off-Campus Hospital Provider-Based Departments

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the furnishing of physicians' services in a hospital outpatient setting (for example, see Ostrom, Carol M. ''Why you might pay twice for one visit to a doctor,'' *Seattle Times.* November 3, 2012, and O'Malley, Ann, Amelia M. Bond, and Robert Berenson. *Rising hospital employment of physicians: better quality, higher costs?* Issue Brief No. 136, Center for Studying Health System Change. August 2011). When a Medicare

beneficiary receives outpatient services in a hospital, Medicare generally pays more in total than when the beneficiary receives those same services in a freestanding clinic or physician office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability for the additional coinsurance for the ''facility fee,'' which is the payment in addition to the physician payment when services are furnished in a hospital. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physician offices become hospital outpatient departments, and has recommended that Medicare pay selected hospital outpatient services at physician fee schedule rates (MedPAC March 2012 *Report to Congress*).

The total l payment (including both Medicare program payment and beneficiary cost-sharing) generally is higher when outpatient services are furnished in the hospital outpatient setting rather than a physician office. Both the PFS and the hospital outpatient prospective payment system (OPPS) establish payment based on the relative resources involved in furnishing a service. As described in section II.B.1.b. of this proposed rule, the relative values for services furnished in the physician office setting under the PFS reflect not only payment for the practitioner's work, but also the direct expenses (clinical labor, medical equipment, and medical supplies) and the indirect expenses (administrative labor, office expense, and all other expenses) typically involved in furnishing the service. Under section 1833(t) of the Act, Medicare provides separate payment through the OPPS to hospitals for certain items and services furnished to registered hospital outpatients that are based on the relativity of the resource costs (labor and capital) involved in furnishing those hospital services. In general, we expect hospitals to have higher overall resource requirements than physician offices because hospitals are required to meet conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community. When services are furnished in the hospital setting, such as in off-campus provider based departments, Medicare pays the physician under the PFS at a typically lower facility payment rate but then also pays the hospital under the OPPS for the facility resources required to furnish the service. The beneficiary pays coinsurance for both the physician PFS payment and the hospital OPPS payment. The term ''facility fee'' refers to this additional hospital outpatient payment.

Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus provider-based departments of the hospital and bill Medicare for services furnished at those locations under the OPPS (for further information on the provider-based regulations at § 413.65, see *http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-65.pdf*). Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment for services furnished in off-campus provider-based departments of the hospital.

To better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, we are considering collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. We have considered several potential methods. Claims-based approaches could include (1) creating a new place of service code for off-campus departments of a provider under 42 CFR 413.65(g)(2) as part of item 24B of the CMS–1500 claim form, comparable to current place of service codes such as ''22 Outpatient'' and ''23 Emergency Room-Hospital'' when physician services are furnished in an off-campus provider-based department, or (2) creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS–1500 claim form for physician services and the UB–04 (CMS form 1450) for hospital outpatient claims. In addition, we also have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, form 2552–10. We note that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount program but this practice is not consistent or standardized. We welcome public comment on the best means for collecting information on the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

B. Misvalued Codes

1. Valuing Services Under the PFS

Section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work; PE; and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to include ''the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service.'' In addition, section 1848(c)(2)(C)(i) of the Act specifies that ''the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.'' Section 1848(c)(1)(B) of the Act defines the PE component as ''the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.'' (See section I.A.2. for more detail on the PE component.) Section 1848(c)(1)(C) of the Act defines the malpractice component as ''the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.'' Sections 1848 (c)(2)(C)(ii) and (iii) of the Act specify that PE and malpractice expense RVUs shall be determined based on the relative PE/malpractice expense resources involved in furnishing the service.

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 3134(a) of the Affordable Care Act added a new section 1848(c)(2)(K) to the Act, which 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 3134(a) of the Affordable Care Act also added a new section 1848(c)(2)(L) to the Act which, requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.A.1. of this proposed rule, each year we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the

American Medical Association/Specialty Society Relative Value Scale Update Committee (AMA RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the AMA 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 physician 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) National Database, 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 AMA RUC. We conduct a clinical 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 appropriate adjustments to the RVUs, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules.

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

a. Background

In its March 2006 Report to the Congress, MedPAC noted that ''misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services.'' In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''when a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PEs decline. 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 PEs rise. In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by the Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years, CMS and the AMA RUC have taken increasingly significant steps to identify and address potentially misvalued codes. As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made the initial recommendations, ''CMS and the AMA RUC have taken several steps to improve the review process.'' Most recently, section 1848(c)(2)(K)(ii) of the Act (as added by section 3134(a) of the Affordable Care Act) directed 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 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. Finally, section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes in all seven of the categories 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. In the current process, we identify potentially misvalued codes for review, and request recommendations from the AMA RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The AMA RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed more than 1,000 potentially misvalued codes to refine work RVUs and direct PE inputs. We have adopted appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS proposed rule, we proposed to identify and review potentially misvalued codes in the category of ''Other codes determined to be appropriate by the Secretary,'' referring to a list of the highest PFS expenditure services, by specialty, that had not been recently reviewed (76 FR 73059 through 73068).

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.

One of the priority categories for review of potentially misvalued codes is services that have not been subject to review since the implementation of the PFS (the so-called ''Harvard-valued codes''). In the CY 2009 PFS proposed rule, we requested that the AMA RUC engage in an ongoing effort to review the remaining Harvard-valued codes, focusing first on the high-volume, low intensity codes (73 FR 38589). For the Fourth Five-Year Review (76 FR 32410), we requested that the AMA RUC review services that have not been reviewed since the original implementation of the PFS with annual utilization greater than 30,000 (Harvard-valued—Utilization > 30,000). In the CY 2013 final rule with comment period, we identify for review the potentially misvalued codes for Harvard-valued services with annual allowed charges that total at least $10,000,000 (Harvard-valued—Allowed charges ≥$10,000,000).

In addition to the Harvard-valued codes, in the same rule we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed physician time and codes with no physician work and have listed physician time).

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 3134(a) of the Affordable Care Act added section 1848(c)(2)(L) of the Act, which specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. 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 seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

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

We have entered into two contracts with outside entities to develop validation models for RVUs. During a 2-year project, the RAND Corporation will use available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design will be informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and AMA RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND will consult with a technical expert panel on model design issues and the test results.

The second contract is with the Urban Institute. Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values, a key focus of the project is collecting data from several practices for services selected by the contractor. The data will be used to develop time estimates. Urban Institute will use a variety of approaches to develop objective time estimates, depending on the type of service, which will be a very resource-intensive part of the project. 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.

3. CY 2014 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 physician time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of physician 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 physician time and intensity from professional and management societies and organizations, such as hospital associations.

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

We did not receive publicly nominated potentially misvalued codes for inclusion in this proposed rule. We look forward to receiving new code nominations for inclusion in the CY 2015 proposed rule to continue with our efforts to identify potentially misvalued codes.

b. Potentially Misvalued Codes

(1) Contractor Medical Director Identified Potentially Misvalued Codes

After publishing the CY final rule with comment period, we began considering additional ways to broaden participation in the process of identifying potentially misvalued codes. We solicited the input of Medicare contractor medical directors (CMDs) in developing a list of potentially misvalued codes. CMDs offer a unique perspective on the Medicare program. Medicare Administrative Contractors administer the Medicare program in their assigned geographic area and each has at least one CMD that serves as its director. As a group, CMDs represent a variety of medical specialties, which makes them a diverse group of physicians capable of providing opinions across the vast scope of services covered under the PFS. In addition to being physicians, they are on the front line of administering the Medicare program; and their offices often serve as the first point of contact for any provider with questions regarding coverage, coding and claims processing. CMDs spend a significant amount of time communicating directly with providers and the health care industry discussing more than just the broad aspects of the Medicare program but also engaging in and facilitating specific discussions around individual services. Through their development of evidence-based local coverage determinations (LCDs), CMDs also have experience developing policy based on research. In consultation with our CMDs, we have identified the following list of codes that we are proposing as potentially misvalued. We include a brief discussion of the reasons for proposing these codes as potentially misvalued.

TABLE 11—CODES IDENTIFIED IN CONSULTATION WITH CMDS AS POTENTIALLY MISVALUED

CPT code	Short descriptor
17311	Mohs 1 stage h/n/hf/g.
17313	Mohs 1 stage t/a/l.
21800	Treatment of rib fracture.
22035	Closed tx spine process fx.
27193	Treat pelvic ring fracture.
33960	External circulation assist.
33961	External circulation assist, each subsequent day.
47560	Laparoscopy w/cholangio.
47562	Laparoscopic cholecystectomy.
47563	Laparo cholecystectomy/graph.
55845	Extensive prostate surgery.
55866	Laparo radical prostatectomy.
64566	Neuroeltrd stim post tibial.
76942	Echo guide for biopsy.

CPT codes 17311 (Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation, head, neck, hands, feet genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks) and 17313 (Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histpathologic preparation including routine stains(s) of the trunk, arms, or legs; first stage, up to 5 tissue blocks) are proposed as potentially misvalued codes because based on CMD comments, we believe that the code may be overvalued.

CPT codes 21800 (Closed treatment of rib fracture, uncomplicated, each), 22305 (Closed treatment of vertebral process fracture(s)) and 27193 (Closed treatment of pelvic ring fracture, dislocation, diastasis or subluxation, without manipulation) is proposed for review. We are considering the appropriateness of having a 90-day global surgical package for a procedure that is performed in settings other than the inpatient setting 33 percent of the time. We believe it is unlikely that it is appropriate for a procedure performed outside of the inpatient hospital setting at this frequency to have such a long global period. CPT codes 33960 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial day) and 33961 (Each subsequent day) are being proposed for review because CMDs were concerned about their current valuation of physician work. The CMD comment states that the service was originally valued when it was used primarily in premature neonates; but the service is now being furnished to adults with severe influenza, pneumonia and respiratory distress syndrome. We are concerned that, while the code currently includes 523 minutes of total physician time with 133 minutes of intraservice time, physicians are not typically furnishing the service over that entire time interval; rather, hospital-employed pump technicians are furnishing much of the work.

CPT codes 47560 (Laparoscopy, surgical; with guided transhepatic cholangiography, without biopsy), 47562 (Cholecystectomy) and 47563 (Cholecystectomy with cholangiography) we are proposing these codes as potentially misvalued because the more extensive code has lower work RVUs than the less extensive codes.

CPT codes 55845 (Prostatectomy, retropubic radical with or without nerve sparing with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes) and 55866 (Laparoscopy, surgical prostatectomy, retropubic radial, including nerve sparing, includes robotic assistance when performed) we are proposing as potentially misvalued because the RVUs for the laparoscopic procedure are higher than for the open procedure and, in general, a laparascopic procedure would not require greater resources than the open procedure.

We are proposing CPT 64566 (Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming) as a potentially misvalued code because we think that the procedure typically is furnished by support staff with supervision as opposed to being furnished by the physician. We are concerned that the current valuation is based on the procedure being furnished by a physician.

We are proposing CPT code 76942 (Ultrasonic guidance for needle placement (for example, biopsy, aspiration, injection, localization device), imaging supervision and interpretation) as a potentially misvalued code because of the high frequency with which it is billed with CPT code 20610 (Arthrocentesis aspiration and/or injection; major joint or bursa (for example, shoulder, hip, knee joint, subacromial bursa) in the CMD's geographic region. The CMD noted that some providers within the contractor's geographic area bill CPT code 76942 with every injection or aspiration of the knee. One CMD suggests that the payment for CPT code 76942 and CPT code 20610 should be combined to reduce the incentive for providers to always provide and bill separately for ultrasound guidance. We note that we are making a proposal regarding the direct PE inputs for CPT code 76942. Our claims data show that the procedure time assumption for CPT code 76942 is longer than the typical procedure with which the code is billed (for example, CPT code 20610). The proposed changes relating to CPT code 76942 are addressed in detail in section II.A.4.b.3. of this proposed rule. We believe that the discrepancy in procedure times and the resulting potentially inaccurate payment raises a fundamental concern regarding the incentive to furnish ultrasound guidance. However, we believe this

concern spans more than just an individual code for ultrasound guidance. Accordingly, we have proposed additional ultrasound guidance codes as potentially misvalued in Table 12. We are seeking public comment on including these codes as potentially misvalued codes. We are also seeking public comment on any similar codes that should be included on this list.

TABLE 12—CPT CODES FOR ULTRASOUND GUIDANCE

CPT code	Short descriptor
76930	Echo guide cardiocentesis.
76932	Echo guide for heart biopsy.
76936	Echo guide for artery repair.
76940	US guide tissue ablation.
76948	Echo guide ova aspiration.
76950	Echo guidance radiotherapy.
76965	Echo guidance radiotherapy.

(2) Improving the Valuation of the Global Surgical Package, Measuring Post-Operative Work

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. Commenters provided a variety of suggestions including setting the all surgical services to a 0-day global period, requiring all E/M services to be separately billed, validating the global surgical packages with the hospital Diagnosis-Related Group length of stay data, and setting documentation standards for post-operative E/M services that could be audited. In addition to receiving the broader comments on measuring post-operative work, we also received a comment from the AMA RUC noting that the hospital and discharge day management services included in the global period for many surgical procedures may have been inadvertently removed from the time file in 2007. With its comment letter, the AMA RUC sent us a time file with updated post-operative visits for the services that arguably we incorrectly displayed with zero visits in the CMS time file. We said in the CY 2013 final rule with comment period that we would review this file and, if appropriate, propose modifications to the physician time file in the CY 2014 PFS proposed rule. We noted in the CY 2013 final rule with comment period that if time had been removed from the physician time file inadvertently, it would not have affected the physician work RVUs or direct PE inputs for these services. It would have a small impact on the indirect allocation of PE at the specialty level, which we would review when we explore this potential time file change.

After extensive review, we believe that the data were deleted from the time file due to an inadvertent error as noted by the AMA RUC. Thus, we are proposing to replace the missing post-operative hospital E/M visit information and time for the 117 codes that were identified by the AMA–RUC and displayed in Table 13. We believe this proposal would populate the physician time file with data that, absent the inadvertent error, would have been present in the time file.

TABLE 13—PROPOSED PHYSICIAN TIME CHANGES FOR CY 2014 POTENTIALLY MISVALUED CODES

CPT code	Short descriptor	AMA RUC-recommended visits				CY 2013 physician time	AMA RUC-recommended physician time
		99231	99232	99238	99291		
19368	Breast reconstruction	4	.....	1	.....	712	770
19369	Breast reconstruction	3	.....	1	.....	657	690
20100	Explore wound neck	2	.....	1	.....	218	266
20816	Replantation digit complete	5	.....	1	.....	671	697
20822	Replantation digit complete	3	.....	1	.....	587	590
20824	Replantation thumb complete	5	.....	1	.....	646	690
20827	Replantation thumb complete	4	.....	1	.....	610	625
20838	Replantation foot complete	8	.....	1	.....	887	986
20955	Fibula bone graft microvasc	6	.....	1	1	867	957
20969	Bone/skin graft microvasc	8	.....	1	.....	1,018	1,048
20970	Bone/skin graft iliac crest	8	.....	1	.....	958	988
20973	Bone/skin graft great toe	5	.....	1	.....	1,018	988
21139	Reduction of forehead	1	.....	1	.....	400	466
21151	Reconstruct midface lefort	2	.....	1	1	567	686
21154	Reconstruct midface lefort	3	.....	1	2	664	853
21155	Reconstruct midface lefort	2	.....	1	2	754	939
21175	Reconstruct orbit/forehead	.....	1	1	2	549	767
21182	Reconstruct cranial bone	.....	1	1	2	619	856
21188	Reconstruction of midface	1	.....	1	.....	512	572
22100	Remove part of neck vertebra	2	.....	1	.....	397	372
22101	Remove part thorax vertebra	3	.....	1	.....	392	387
22110	Remove part of neck vertebra	6	.....	1	.....	437	479
22112	Remove part thorax vertebra	7	.....	1	.....	507	530
22114	Remove part lumbar vertebra	7	.....	1	.....	517	530
22210	Revision of neck spine	7	.....	1	.....	585	609
22212	Revision of thorax spine	7	.....	1	.....	610	640
22214	Revision of lumbar spine	7	.....	1	.....	585	624
22220	Revision of neck spine	7	.....	1	.....	565	585
22222	Revision of thorax spine	8	.....	1	.....	630	651
22224	Revision of lumbar spine	8	.....	1	.....	620	666
22315	Treat spine fracture	1	.....	1	.....	257	252
22325	Treat spine fracture	6	.....	1	.....	504	528
22326	Treat neck spine fracture	6	.....	1	.....	452	480
22327	Treat thorax spine fracture	9	.....	1	.....	505	604
22548	Neck spine fusion	8	.....	1	1	532	673
22556	Thorax spine fusion	3	.....	1	1	525	557
22558	Lumbar spine fusion	2	.....	1	1	502	525

TABLE 13—PROPOSED PHYSICIAN TIME CHANGES FOR CY 2014 POTENTIALLY MISVALUED CODES—Continued

CPT code	Short descriptor	AMA RUC-recommended visits				CY 2013 physician time	AMA RUC-recommended physician time
		99231	99232	99238	99291		
22590	Spine & skull spinal fusion	3		1		532	501
22595	Neck spinal fusion	6		1		492	521
22600	Neck spine fusion	6		1		437	490
22610	Thorax spine fusion	8		1		468	549
22630	Lumbar spine fusion	3		1		501	487
22800	Fusion of spine	7		1		517	571
22802	Fusion of spine	4		1		552	538
22804	Fusion of spine	5		1		630	595
22808	Fusion of spine	5		1		553	530
22810	Fusion of spine	5		1		613	595
22812	Fusion of spine	8		1		666	700
31582	Revision of larynx	8		1		489	654
32650	Thoracoscopy w/pleurodesis	2		1		322	290
32656	Thoracoscopy w/pleurectomy	3		1		419	377
32658	Thoracoscopy w/sac fb remove	1		1		362	330
32659	Thoracoscopy w/sac drainage	2		1		414	357
32661	Thoracoscopy w/pericard exc	1		1		342	300
32664	Thoracoscopy w/th nrv exc	1		1		362	330
32820	Reconstruct injured chest	4		1	5	631	854
33236	Remove electrode/thoracotomy	4		1		258	346
33237	Remove electrode/thoracotomy	5		1		378	456
33238	Remove electrode/thoracotomy	5		1		379	472
33243	Remove eltrd/thoracotomy	5		1		504	537
33321	Repair major vessel	8		1		751	754
33332	Insert major vessel graft	8		1		601	604
33401	Valvuloplasty open	8		1		830	661
33403	Valvuloplasty w/cp bypass	8		1		890	638
33417	Repair of aortic valve	3		1	3	740	750
33472	Revision of pulmonary valve	1		1	5	665	780
33502	Coronary artery correction	3		1	3	710	688
33503	Coronary artery graft	6		1	3	890	838
33504	Coronary artery graft	5		1	3	740	789
33600	Closure of valve	6		1		800	628
33602	Closure of valve	6		1		770	628
33606	Anastomosis/artery-aorta	8		1		860	728
33608	Repair anomaly w/conduit	5		1		800	668
33690	Reinforce pulmonary artery	3		1	3	620	636
33702	Repair of heart defects	1		1	4	663	751
33722	Repair of heart defect	5		1		770	608
33732	Repair heart-vein defect	5		1		710	578
33735	Revision of heart chamber	3		1	4	740	770
33736	Revision of heart chamber	5		1		710	548
33750	Major vessel shunt	2		1	3	680	722
33764	Major vessel shunt & graft	2		1	4	710	750
33767	Major vessel shunt	5		1		800	608
33774	Repair great vessels defect	1		1	7	845	998
33788	Revision of pulmonary artery	3		1	3	770	736
33802	Repair vessel defect	3		1	2	558	556
33803	Repair vessel defect	3		1	2	618	586
33820	Revise major vessel	1		1	1	430	414
33824	Revise major vessel	1		1	3	588	615
33840	Remove aorta constriction	2		1	3	588	639
33845	Remove aorta constriction	1		1	3	710	726
33851	Remove aorta constriction	2		1	3	603	700
33852	Repair septal defect	2		1	3	663	719
33853	Repair septal defect	8		1		800	668
33917	Repair pulmonary artery	5		1		740	608
33920	Repair pulmonary atresia	6		1		800	658
33922	Transect pulmonary artery	5		1		618	546
33974	Remove intra-aortic balloon	1		1		406	314
34502	Reconstruct vena cava	6		1		793	741
35091	Repair defect of artery	11		1	2	597	790
35694	Arterial transposition	2		1		468	456
35901	Excision graft neck	4		1		484	482
35903	Excision graft extremity	3		1		408	416
47135	Transplantation of liver	23		1		1,501	1,345
47136	Transplantation of liver	28		1		1,301	1,329
49422	Remove tunneled ip cath	1		1		154	182
49429	Removal of shunt	6		1		249	317
50320	Remove kidney living donor	4		1		480	524

TABLE 13—PROPOSED PHYSICIAN TIME CHANGES FOR CY 2014 POTENTIALLY MISVALUED CODES—Continued

CPT code	Short descriptor	AMA RUC-recommended visits				CY 2013 physician time	AMA RUC-recommended physician time
		99231	99232	99238	99291		
50845	Appendico-vesicostomy	5	.....	1	.....	685	613
56632	Extensive vulva surgery	7	.....	1	.....	835	683
60520	Removal of thymus gland	2	.....	1	2	406	474
60521	Removal of thymus gland	5	.....	1	.....	457	445
60522	Removal of thymus gland	7	.....	1	.....	525	533
61557	Incise skull/sutures	3	.....	1	.....	529	510
63700	Repair of spinal herniation	3	.....	1	.....	399	401
63702	Repair of spinal herniation	3	.....	1	.....	469	463
63704	Repair of spinal herniation	8	.....	1	.....	534	609
63706	Repair of spinal herniation	8	.....	1	.....	602	679

(3) Codes With Higher Total Medicare Payments in Office Than in Hospital or ASC

We are proposing to address nearly 200 codes that we believe have misvalued resource inputs. These are codes for which the total PFS payment when furnished in an office or other nonfacility setting would exceed the total Medicare payment (the combined payment to the facility and the professional) when the service is furnished in a facility, either a hospital outpatient department or an ASC.

For services furnished in a facility setting we would generally expect the combined payment to the facility and the practitioner to exceed the PFS payment made to the professional when the service is furnished in the nonfacility setting. This payment differential is expected because it reflects the greater costs we would expect to be incurred by facilities relative to physicians furnishing services in offices and other non-facility settings. These greater costs are due to higher overhead resulting from differences in regulatory requirements and for facilities, such as hospitals, maintaining the capacity to furnish services 24 hours per day and 7 days per week. However, when we analyzed such payments, we identified nearly 300 codes that would result in greater Medicare payment in the nonfacility setting than in the facility setting. We believe these anomalous site-of-service payment differentials are the result of inaccurate resource input data used to establish rates under the PFS.

In this proposed rule, we are proposing to address these misvalued codes. Specifically, we are proposing to refine the PE methodology to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined payment under the PFS and the OPPS (or the ASC payment system) when the service is furnished in the facility setting. We believe this is an efficient way to address these significant anomalies within the PE methodology and more appropriately value these services. We discuss this proposal in more detail in section II.A.4.b.3.

4. The Multiple Procedure Payment Reduction Policy

Medicare has long employed multiple procedure payment reduction (MPPR) policies to adjust payment to more appropriately reflect reduced resources involved with furnishing services that are frequently furnished together. Under these policies, we reduce payment for the second and subsequent services within the same MPPR category furnished in the same session or same day. These payment reductions reflect efficiencies that typically occur in either the PE or professional work or both when services are furnished together. With the exception of a few codes that are always reported with another code, the PFS values services independently to recognize relative resources involved when the service is the only one furnished in a session. Although some of our MPPR policies precede the Affordable Care Act, MPPRs can address the fourth category of potentially misvalued codes identified in section 1848(c)(2)(K) of the Act, as added by the Affordable Care Act, which is ''multiple codes that are frequently billed in conjunction with furnishing a single service'' (see 75 FR 73216). We are not proposing any new MPPRs in this proposed rule, but the following sections describe the history of MPPRs and the services currently covered by MPPRs.

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same beneficiary by a single physician, or physicians in the same group practice, on the same day, largely based on the presence of efficiencies in the PE and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with this same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to the Congress on Medicare Payment Policy, for CY 2006 PFS, we extended the MPPR policy to the TC of certain diagnostic imaging procedures furnished on contiguous areas of the body in a single session (70 FR 70261). This MPPR policy recognizes that for the second and subsequent imaging procedures furnished in the same session, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent imaging services in the same session and, because equipment time and indirect costs are allocated based on clinical labor time, we also reduced those accordingly.

The imaging MPPR policy originally applied to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region, and only applied to procedures furnished in a single session involving contiguous body areas within a family of codes. Additionally, this MPPR policy originally applied to TC-only services and to the TC of global services, but not to professional component (PC) services.

There have been several revisions to this policy since it was originally adopted. Under the current imaging

MPPR policy, full payment is made for the TC of the highest paid procedure, and payment for the TC is reduced by 50 percent for each additional procedure subject to this MPPR policy. We originally planned to phase in the imaging MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007 (70 FR 70263). However, section 5102(b) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on December 20, 2006) amended the statute to place a cap on the PFS payment amount for most imaging procedures at the amount paid under the hospital outpatient prospective payment system (OPPS). In view of this new OPPS payment cap, we decided in the CY 2006 PFS final rule with comment period that it would be prudent to retain the imaging MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the imaging MPPR policy from the PFS budget neutrality provision. Effective July 1, 2010, section 1848(b)(4)(C) of the Act increased the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent. Section 1848(c)(2)(B)(v)(IV) of the Act exempted the reduced expenditures attributable to this further change from the PFS budget neutrality provision.

In the July 2009 U.S. Government Accountability Office (GAO) report entitled, *Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided Together,* the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician to the same beneficiary on the same day. The GAO report recommended the following: (1) Expanding the existing imaging MPPR policy for certain services to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain nonsurgical, nonimaging services are furnished together. The GAO report also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In its March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services. In the CY 2009 and CY 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

Section 1848(c)(2)(K) of the Act specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, in the CY 2010 final rule with comment period, we implemented a limited expansion of the imaging MPPR policy to additional combinations of imaging services.

Effective January 1, 2011, the imaging MPPR applies regardless of code family; that is, the policy applies to multiple imaging services furnished within the same family of codes or across families. This policy is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. The current imaging MPPR policy applies to CT and CTA, MRI and MRA, and ultrasound procedures furnished to the same beneficiary in the same session, regardless of the imaging modality, and is not limited to contiguous body areas.

As we noted in the CY 2011 PFS final rule with comment period (75 FR 73228), although section 1848(c)(2)(B)(v)(VI) of the Act specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS budget neutrality adjustment, it does not apply to reduced expenditures attributable to our policy change regarding additional code combinations across code families (noncontiguous body areas) that are subject to budget neutrality under the PFS. The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 1848(c)(2)(K) of the Act, on January 1, 2011, we implemented an MPPR for therapy services. The MPPR applies to separately payable ''always therapy'' services, that is, services that are only paid by Medicare when furnished under a therapy plan of care. As we explained in the CY 2011 PFS final rule with comment period (75 FR 73232), the therapy MPPR does not apply to contractor-priced codes, bundled codes, or add-on codes.

This MPPR for therapy services was first proposed in the CY 2011 proposed rule (75 FR 44075) as a 50 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single beneficiary in a single day. It applies to services furnished by an individual or group practice or ''incident to'' a physician's service. However, in response to public comments, in the CY 2011 PFS final rule with comment period (75 FR 73232), we adopted a 25 percent payment reduction to the PE component of the second and subsequent therapy services for multiple ''always therapy'' services furnished to a single beneficiary in a single day.

Subsequent to publication of the CY 2011 PFS final rule with comment period, section 3 of the Physician Payment and Therapy Relief Act of 2010 (PPTRA) (Pub. L. 111–286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services for which payment is made under a fee schedule under section 1848 of the Act (which are services furnished in office settings, or non-institutional services). The payment reduction percentage remained at 25 percent for therapy services furnished in institutional settings. Section 4 of the PPTRA exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS budget neutrality provision. Section 633 of the ATRA revised the reduction to 50 percent of the PE component for all settings, effective April 1, 2013. Therefore, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 50 percent for both institutional and non-institutional services.

This MPPR policy applies to multiple units of the same therapy service, as well as to multiple different ''always therapy'' services, when furnished to the same beneficiary on the same day. The MPPR applies when multiple therapy services are billed on the same date of service for one beneficiary by the same practitioner or facility under the same National Provider Identifier (NPI), regardless of whether the services are furnished in one therapy discipline or multiple disciplines, including physical therapy, occupational therapy, or speech-language pathology.

The MPPR policy applies in all settings where outpatient therapy services are paid under Part B. This includes both services that are furnished in the office setting and paid under the PFS, as well as institutional services that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid for outpatient therapy services at rates based on the PFS.

In its June 2011 Report to Congress, MedPAC highlighted continued growth in ancillary services subject to the in-office ancillary services exception. The in-office ancillary exception to the general prohibition under section 1877 of the Act as amended by the Ethics in Patient Referrals Act, also known as the Stark law, allows physicians to refer Medicare beneficiaries for designated health services, including imaging, radiation therapy, home health care, durable medical equipment, clinical laboratory tests, and physical therapy, to entities with which they have a financial relationship under specific conditions. MedPAC recommended that we apply a MPPR to the PC of diagnostic imaging services furnished by the same practitioner in the same session as one means to curb excess self-referral for these services. The GAO already had made a similar recommendation in its July 2009 report.

In continuing to apply the provisions of section 1848(c)(2)(K) of the Act regarding potentially misvalued codes that result from ''multiple codes that are frequently billed in conjunction with furnishing a single service,'' in the CY 2012 final rule (76 FR 73071), we expanded the MPPR to the PC of Advanced Imaging Services (CT, MRI, and Ultrasound), that is, the same list of codes to which the MPPR on the TC of advanced imaging already applied. Thus, this MPPR policy now applies to the PC and the TC of certain diagnostic imaging codes. Specifically, we expanded the payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging services furnished by the same physician (or by two or more physicians in the same group practice) to the same beneficiary in the same session on the same day. However, in response to public comments, in the CY 2012 PFS final rule with comment period, we adopted a 25 percent payment reduction to the PC component of the second and subsequent imaging services.

Under this policy, full payment is made for the PC of the highest paid advanced imaging service, and payment is reduced by 25 percent for the PC for each additional advanced imaging service furnished to the same beneficiary in the same session. This policy was based on the expected efficiencies in furnishing multiple services in the same session due to duplication of physician work, primarily in the pre- and post-service periods, but with some efficiencies in the intraservice period.

This policy is consistent with the statutory requirement for the Secretary to identify, review, and adjust the relative values of potentially misvalued services under the PFS as specified by section 1848(c)(2)(K) of the Act. This policy is also consistent with our longstanding policies on surgical and nuclear medicine diagnostic procedures, under which we apply a 50 percent payment reduction to second and subsequent procedures. Furthermore, it was responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010 and June 2011) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

In the CY 2013 final rule (77 FR 68933), we expanded the MPPR to the TC of certain cardiovascular and ophthalmology diagnostic tests. Although we proposed a 25 percent reduction for both diagnostic cardiovascular and ophthalmology services, we adopted a 20 percent reduction for ophthalmology services in the final rule with comment period (77 FR 68941) in response to public comments. For diagnostic cardiovascular services, full payment is made for the procedure with the highest TC payment, and payment is reduced by 25 percent for the TC for each additional procedure furnished to the same patient on the same day. For diagnostic ophthalmology services, full payment is made for the procedure with the highest TC payment, and payment is reduced by 20 percent for the TC for each additional procedure furnished to the same patient on the same day.

Although we are not proposing any new MPPR policies for CY 2014, we continue to look at expanding the MPPR based on efficiencies when multiple procedures are furnished together. Any specific proposals would be presented in future rulemaking and subject to further public comment.''

The complete list of services subject to the MPPRs on diagnostic imaging services, therapy services, diagnostic cardiovascular services and diagnostic ophthalmology services is shown in Addenda F through J.

C. Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA, which amended section 1848(c) of the Act, required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review and, if necessary, adjust RVUs no less often than every 5 years. The first review and update of resource-based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs, see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), malpractice RVUs for new and revised codes effective before the next five-year review of malpractice RVUs (for example, effective CY 2011 through CY 2014, assuming that the next review of malpractice RVUs occurs for CY 2015) are determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or ''scale'') the malpractice RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the malpractice RVU for the revised code would be increased by 10 percent over the source code malpractice RVU. This approach presumes the same risk factor for the new/revised code and source code but

uses the work RVU for the new/revised code to adjust for the difference in risk attributable to the variation in work between the two services.

For CY 2014, we will continue our current approach for determining malpractice RVUs for new/revised codes. We will publish a list of new/revised codes and the malpractice crosswalks used for determining their malpractice RVUs in the final rule with comment period. The CY 2014 malpractice RVUs for new/revised codes will be implemented in the CY 2014 PFS final rule with comment period. These RVUs will be subject to public comment. They will then be finalized in the CY 2015 PFS final rule with comment period.

D. Medicare Economic Index (MEI)

1. Revising of the Medicare Economic Index (MEI)

a. Background

The Medicare Economic Index (MEI) is authorized under section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. Beginning July 1, 1975, and continuing through today, the MEI has met this requirement by reflecting the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. This index is comprised of two broad categories: (1) Physicians' own time; and (2) physicians' practice expense (PE).

The current form of the MEI was described in the November 25, 1992 **Federal Register** (57 FR 55896) and was based in part on the recommendations of a Congressionally-mandated meeting of experts held in March 1987. Since that time, the MEI has been updated or revised on four instances. First, the MEI was rebased in 1998 (63 FR 58845), which moved the cost structure of the index from 1992 data to 1996 data. Second, the methodology for the productivity adjustment was revised in the CY 2003 PFS final rule with comment period (67 FR 80019) to reflect the percentage change in the 10-year moving average of economy-wide private nonfarm business multifactor productivity. Third, the MEI was rebased in 2003 (68 FR 63239), which moved the cost structure of the index from 1996 data to 2000 data. Fourth, the MEI was rebased in 2011 (75 FR 73262), which moved the cost structure of the index from 2000 data to 2006 data.

The terms ''rebasing'' and ''revising'', while often used interchangeably, actually denote different activities. Rebasing refers to moving the base year for the structure of costs of an input price index, while revising relates to other types of changes such as changing data sources, cost categories, or price proxies used in the input price index. For CY 2014, we are proposing to revise the MEI based on the recommendations of the MEI Technical Advisory Panel (TAP). We are not rebasing the MEI and will continue to use the data from 2006 to estimate the cost weights, since these are the most recently available, relevant, and complete data we have available to develop these weights. In the following sections of this proposed rule, we detail our proposals regarding reorganization of cost categories, our rationale for selecting the price proxies in the MEI, and the results of the proposed revisions to the MEI based on the MEI TAP recommendations.

b. MEI Technical Advisory Panel (TAP) Recommendations

In the CY 2011 PFS final rule (77 FR 68892), we proposed to convene a MEI TAP that would review all aspects of the MEI, including the inputs, input weights, price-measurement proxies, and productivity adjustment. The MEI TAP was to assess the relevance and accuracy of these inputs to current physician practices. The MEI TAP's analysis and recommendations would be considered in future rulemaking to ensure that the MEI accurately and appropriately meets its intended statutory purpose.

The MEI TAP was established by the Secretary under 42 U.S.C. 217a and was governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463, enacted on October 6, 1972), as amended, 5 U.S.C. App. The Panel's deliberations were made in accordance with the FACA, which means that the meetings were conducted in public and stakeholders were given the opportunity to share their evidence and views with panel members.

The MEI TAP consisted of five members and held three meetings in 2012: May 21; June 25; and July 11. It produced 8 findings and 13 recommendations for consideration by CMS. Background on the MEI TAP members, meeting transcripts for all three meetings, and the MEI TAP's final report, including all findings and recommendations are available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.html.* It is possible to implement some of the recommendations immediately, while more in-depth research is required to implement several of the recommendations.

For CY 2014, we are proposing to implement 10 of the 13 recommendations made by the MEI TAP. These proposed changes only involve revising the MEI categories, cost shares, and price proxies. Again, we are not proposing to rebase the MEI at this time since the MEI TAP concluded that there is not a reliable, ongoing source of data to maintain the MEI. After acknowledging that there are no additional data to support further rebasing of the MEI at this time, the MEI TAP recommended that CMS' Office of the Actuary (OACT) identify and evaluate additional data sources that may allow for more frequent updates to the MEI's cost categories and their respective weights. Some of the possible data sources the MEI TAP suggested we consider are:

- The Medical Group Management Association's (MGMA) Cost Survey
- The Bureau of the Census Services Annual Survey (SAS)
- Pending feasibility, a CMS survey, possibly conducted jointly with the American Medical Association, that focuses exclusively on physician expenses as they relate to the MEI. The Panel notes that the lead time to conceive, develop, fund, and administer such a survey would likely be considerable.
- Alternatively, and again pending feasibility, CMS could obtain more robust data by means of detailed formal cost reports based on a methodologically sound sample of physician practices. Whether the degree of improvement in the MEI would warrant the cost associated with the process would be an important consideration.

As such, we will continue to investigate possible data sources, including an assessment of whether using self-employed physician data for the MEI cost weights, continues to be the most appropriate approach.

c. Overview of Proposed Revisions

The MEI was last rebased and revised in the CY 2011 PFS final rule with comment period (75 FR 73262–73275). The current base year for the MEI is 2006, which means that the cost weights in the index reflect physicians' expenses in 2006. The details of the methodology used to determine the 2006 cost shares were provided in the CY 2011 PFS

proposed rule and finalized in the CY 2011 PFS final rule with comment period (75 FR 40087 and 75 FR 73262, respectively). We are proposing to make the following revisions to the 2006-based MEI:

(1) Reclassify and Revise Certain Cost Categories

- Reclassify expenses for non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation.
- Revise the physician wage and benefit split so that the cost weights are more in line with the definitions of the price proxies used for each category.
- Add an additional subcategory under non-physician compensation for health-related workers.
- Create a new cost category called ''All Other Professional Services'' that includes expenses covered in the current MEI categories: ''All Other Services'' and ''Other Professional Expenses.'' The proposed ''All Other Professional Services'' category would be further disaggregated into appropriate occupational subcategories.
- Create an aggregate cost category called ''Miscellaneous Office Expenses'' that would include the expenses for ''Rubber and Plastics,'' ''Chemicals,'' ''All Other Products,'' and ''Paper.''

(2) Revise Price Proxies

- Revise the price proxy for physician wages and salaries from the Average Hourly Earnings (AHE) for the Total Private Nonfarm Economy for Production and Nonsupervisory Workers to the ECI for Wages and Salaries, Professional and Related Occupations, Private Industry.
- Revise the price proxy for physician benefits from the ECI for Benefits for the Total Private Industry to the ECI for Benefits, Professional and Related Occupations, Private Industry.
- Use the ECI for Wages and Salaries and the ECI for Benefits of Hospital, Civilian workers (private industry) as the price proxies for the new category of non-physician health-related workers.
- Use ECIs to proxy the Professional Services occupational subcategories that reflect the type of professional services purchased by physicians' offices.
- Revise the price proxy for the fixed capital category from the CPI for Owners' Equivalent Rent of Residences to the PPI for Lessors of Nonresidential Buildings (NAICS 53112).

d. Revising Expense Categories in the MEI

The MEI is used as part of the Sustainable Growth Rate (SGR) methodology to update the PFS and represents the price component of that update. The proposed expense categories in the MEI, along with their respective weights, are primarily derived from data collected in the 2006 AMA Physician Practice Information Survey (PPIS) for self-employed physicians representing 42 medical specialties and selected self-employed non-Medical Doctor (non-MD) specialties. Data for non-MD specialties were collected in a supplemental survey of the PPIS survey questionnaire. We included the data from the following non-medical specialties in the MEI cost weight calculations (optometrists, oral surgeons, podiatrists, and chiropractors) specialties in the MEI cost weight calculations consistent with the definition of the term ''physician'' in section 1861(r) of the Act. In summary, the term ''physician'' when used in connection with the performance of functions or actions an individual is legally authorized to perform means the following: (1) A doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a doctor of podiatric medicine; (4) a doctor of optometry; or (5) a chiropractor. For a complete definition, please see section 1861(r) of the Act. We are not proposing to change the data source we used to establish the major MEI cost weights, and therefore, we propose to continue to use of the 2006 AMA PPIS physician expense data at this time. Data for the dental medicine specialty are not included in the weights since the PPIS supplemental collection effort did not survey this specialty.

We are not proposing any changes in the methodology for estimating the cost shares as finalized in the CY 2011 PFS final rule with comment period (75 FR 73263–73267). For CY 2014, we are proposing to revise the classification of certain expenses within the 2006-based MEI. The following sections describe the details of the proposed revisions for each of the categories and the rationale for the proposed changes. We also provide the Panel recommendation that is the impetus for each of the proposed revisions.

(1) Overall MEI Cost Weights

Table 14 lists the set of mutually exclusive and exhaustive cost categories and weights that make up the proposed revised MEI as compared to the current MEI cost categories.

The physician compensation cost weight under the proposed revised MEI is 2.600 percentage points higher than the physician compensation weight in the current MEI. This occurs because of the proposed reclassification of expenses for non-physician clinical staff that can bill independently from non-physician compensation to physician compensation. This change lowers the PE cost weight by 2.600 percent as well, all of which comes from a lower weight for non-physician compensation. The remaining MEI cost weights are unchanged.

The proposed revised MEI includes four new detailed cost categories and two new sub-aggregate cost categories. The proposed new detailed cost categories are:

- Health-related, non-physician wages and salaries.
- Professional, scientific, and technical services.
- Administrative support and waste management services.
- All other services.

The proposed new sub-aggregate categories are:

- Non-health, non-physician wages.
- Miscellaneous office expenses.

The proposed revised MEI excludes two sub-aggregate categories that were included in the current 2006-based MEI. The sub-aggregate categories we propose to remove are:

- Office expenses.
- Drugs & supplies.

TABLE 14—PROPOSED REVISED 2006 MEI COST CATEGORIES AND, WEIGHTS COMPARED TO THE CURRENT 2006 MEI COST CATEGORIES AND WEIGHTS

Current MEI (2006 = 100), finalized in the CY2011 PFS final rule		Proposed revised MEI (2006 = 100), CY2014 PFS proposed rule	
Cost category	Current weights (percent)	Revised weights (percent)	Revised cost category
Physician Compensation	48.266	50.866	Physician Compensation.
Wages and Salaries	43.881	43.641	Wages and Salaries.

TABLE 14—PROPOSED REVISED 2006 MEI COST CATEGORIES AND, WEIGHTS COMPARED TO THE CURRENT 2006 MEI COST CATEGORIES AND WEIGHTS—Continued

Current MEI (2006 = 100), finalized in the CY2011 PFS final rule		Proposed revised MEI (2006 = 100), CY2014 PFS proposed rule	
Cost category	Current weights (percent)	Revised weights (percent)	Revised cost category
Benefits	4.386	7.225	Benefits.
Practice Expense	51.734	49.134	Practice Expense.
Non-physician compensation	19.153	16.553	Non-physician compensation.
Non-physician wages	13.752	11.885	Non-physician wages.
		7.249	Non-health, non-physician wages.
P&T	6.006	0.800	Professional and Related.
Management	1.446	1.529	Management.
Clerical	4.466	4.720	Clerical.
Services	1.834	0.200	Services.
		4.636	Health related, non-physician wages.
Non-physician benefits	5.401	4.668	Non-physician benefits.
Other Practice Expense	26.308	32.581	Other Practice Expense.
Office expenses	20.035		
Utilities	1.266	1.266	Utilities.
		2.478	Miscellaneous Office Expenses.
Chemicals	0.723	0.723	Chemicals.
Paper	0.656	0.656	Paper.
Rubber & Plastics	0.598	0.598	Rubber & Plastics.
		0.500	All other products.
Telephone	1.501	1.501	Telephone.
Postage	0.898	0.898	Postage.
All other services	3.581	8.095	All Other professional services.
		2.592	Professional, scientific, & technical services.
		3.052	Administrative support & waste management.
		2.451	All other services.
All other products	0.500		
Capital	10.310	10.310	Capital.
Fixed Capital	8.957	8.957	Fixed Capital.
Moveable Capital	1.353	1.353	Moveable Capital.
Professional Liability Insurance	4.295	4.295	Professional Liability Insurance.
Medical Equipment	1.978	1.978	Medical Equipment.
Drugs and Supplies	1.760		
Prescription Drugs	0.000		
Medical supplies	1.760	1.760	Medical supplies.
Other Professional Expenses	4.513		
All other	4.513		
Total MEI	100.000	100.000	Total MEI.

* The term (2006 = 100) refers to the base year of the MEI

(2) Physician Compensation (Own time).

The component of the MEI that reflects the physician's own time is represented by the net income portion of business receipts. The 2006 cost weight associated with the physician's own time (otherwise referred to as the Physician's Compensation cost weight) is based on 2006 AMA PPIS data for mean physician net income (physician compensation) for self-employed physicians and for the selected self-employed specialties referenced previously in this rule. Expenses for employed physician compensation are combined with expenses for self-employed physician compensation to obtain an aggregate Physician Compensation cost weight. Based on this methodology, the Physician Compensation cost weight in the current MEI is 48.266 percent.

As discussed in the CY 2011 PFS final rule with comment period (75 FR 73265), when determining this weight, we classified the expenses for non-physician clinical staff that can bill Medicare independently under non-physician compensation, which is where these expenses have historically been apportioned in the MEI. The AMA PPIS survey question that collected the data for the clinical personnel who can independently bill, such as nurse practitioners, physician assistants, and other clinical personnel, captured these expenses under non-physician compensation. Additionally, prior AMA surveys captured these expenses as non-physician compensation costs.

The Panel reviewed this methodology and Recommendation 3.2 was that:

''OACT evaluate the appropriate classification of the expenses associated with non-physician clinical staff who can bill Medicare independently. Among the factors OACT should consider are:

- Any definition of 'physicians' that exists under current law in relation to the Medicare PFS and whether these definitions might limit OACT's ability to make changes;
- Whether time for non-physician staff who can bill independently is included among the inputs to the PE RVU methodology under the Medicare PFS (that is, is the treatment of this input under the PE RVU methodology consistent with that under the MEI);
- Whether there is any evidence these staff do not spend the majority of their time providing 'physicians' services' as defined by Medicare; and
- The extent to which those who can bill independently actually do so.''

We are proposing to reclassify these expenses to physician compensation for several reasons:

- These types of practitioners furnish services that are similar to those furnished by physicians.
- If billing independently, these practitioners would be paid at a percentage of the physicians' services or in certain cases at the same rate as physicians.
- The expenses related to the work components for the RVUs would include work from clinical staff that can bill independently. Therefore, it would improve consistency with the RVU payments to include these expenses as physician compensation in the MEI.

The effect of moving the expenses related to clinical staff that can bill independently is to increase the physician compensation cost share by 2.600 percentage points and reduces non-physician compensation costs by the same amount. The physician compensation cost share for the proposed revised MEI is 50.866 percent compared to the physician compensation cost share of 48.266 percent in the current MEI.

Within the physician compensation cost weight, the MEI includes a separate weight for wages and salaries and a separate weight for benefits. Under the current 2006-based MEI, the ratio for wages and salaries, and benefits was calculated using data from the PPIS. Self-employed physician wages and salaries accounted for 92.3 percent of physician earnings while physician benefits accounted for the remaining 7.8 percent. For employed physician payroll, the distributions for wages and salaries, and benefits for 2006 were 85.8 percent and 14.2 percent, respectively. This ratio was determined by calculating a weighted average of available IRS Statistics of Income (SOI) data for partnerships, corporations, and S-corporations specific to physicians and outpatient care centers. Combining the information on self-employed and employed physicians produced a physician wages & salaries cost weight of 43.880 percent and a physician benefits cost weight of 4.386 percent, in the current MEI.

Recommendation 3.1 stated:

> The Panel recommends that OACT revise the Physician Wages and Salaries and Physician Benefit cost weights in the 2006-based MEI. OACT should determine the cost weights for wages and benefits to ensure they are consistent with the definitions in the Employment Cost Index. Specifically, OACT should consider estimating the proportion of the Physician Wages and Salaries cost weight associated with physicians' retirement benefits, and reclassifying that percentage into the Physician Benefits cost weight to be consistent with the costs included in the ECI for Wages and Salaries and the ECI for Benefits price proxies. Evaluation of the PPIS data determined that retirement benefits were included in the Physician Wages and Salaries cost weight while the associated price change is currently reflected in the ECI for Benefits.

We are proposing to revise the wage and benefit split used for physician compensation. Specifically, we are proposing to apply the distribution from the SOI data to both self-employed and employed physician compensation. In reviewing the detailed AMA PPIS survey questions, it was clear that self-employed physician benefits were mainly comprised of insurance costs while other benefits such as physician retirement, paid leave, and payroll taxes were likely included in physician wages and salaries.

By definition, the price proxy used for physician benefits, which is an Employment Cost Index (ECI) concept, includes retirement savings. Thus, using the AMA PPIS data produces a definitional inconsistency between the cost weight and the price proxy. Therefore, we propose to use the data on wages and salaries, and employee benefits from the SOI for Offices of Physicians and Dentists for partnerships and corporations for both self-employed and employed physicians. From the SOI data, benefit expenses were estimated by summing the partnership data for retirement plans and employee benefit programs with corporation data for pension, profit-sharing plans and employee benefit programs. For 2006, the split between wages and salaries, and benefits was 85.8 percent and 14.2 percent, respectively. Retirement/pension plans account for about 60 percent of total benefits. The SOI data do not classify paid leave and supplemental pay as a benefit.

Combining the impact of classifying compensation for non-physicians that can bill independently as physician compensation with the use of the SOI data, the physician wages and salary cost share in the proposed revised MEI is lower than the current MEI by 0.240 percentage points. These two methodological changes result in an increase in the physician benefit cost share in the proposed revised MEI of 2.839 percentage points. As a result, the physician wages and salary cost share for the proposed revised MEI is 43.641 percent and the physician benefit cost share for the proposed revised MEI is 7.225 percent.

(3) Physician's Practice Expenses

To determine the PE cost weights, we use mean expense data from the 2006 PPIS survey. The derivation of the weights and categories for practice expenses is the same as finalized in the CY 2011 PFS final rule with comment period (75 FR 73264–73267), except where noted below.

(a) Non-physician Employee Compensation

The cost weight for Non-physician Employee Compensation was developed using the 2006 AMA PPIS mean expenses for these costs. As discussed previously, for CY 2014 we are proposing to exclude the expenses related to non-physician clinical staff that can bill independently from this cost category. Moving the expenses related to the clinical staff that can bill independently out of non-physician compensation costs decreases the share by 2.600 percentage points. The non-physician compensation cost share for the proposed revised MEI is 16.553 percent compared to the current physician compensation cost share of 19.153 percent.

We are proposing to use the same method as finalized in the CY 2011 PFS final rule to split the non-physician compensation between wages and benefits. For reference, we use 2006 BLS Employer Costs for Employee Compensation (ECEC) data for the Health Care and Social Assistance (private industry). Data for 2006 in the ECEC for Health Care and Social Assistance indicate that wages and benefits are 71.8 percent and 28.2 percent of compensation, respectively. The non-physician wage and benefit cost shares for the proposed revised MEI are 11.885 percent and 4.668 percent, respectively; for the current MEI, the non-physician wage and benefit cost shares are 13.752 percent and 5.401 percent, respectively.

The current 2006-based MEI further disaggregated the non-physician wages into four occupational subcategories, the details of this method can be found in 75 FR 73264–73265. The MEI TAP Recommendation 4.4 stated:

> ''The Panel recommends the disaggregation of the Non-Physician Compensation costs to include an additional category for health-related workers. This disaggregation would allow for health-related workers to be separated from non-health-related workers. CMS should rely directly on PPIS data to estimate the health-related non-physician compensation cost weights. The non-health, non-physician wages should be further disaggregated based on the Current Population Survey and Occupational Employment Statistics data.''

We propose to implement this recommendation using expenses reported on the AMA PPIS for non-

physician, non-health-related workers. The survey question asks for the expenses for: ''Non-clinical personnel involved primarily in administrative, secretarial or clerical activities (Including transcriptionists, medical records personnel, receptionists, schedulers and billing staff, coding staff, information technology staff, and custodial personnel).'' The non-physician, non-health-related wage cost share for the proposed revised MEI is 7.249 percent.

For wage costs of non-physician, health-related workers, the survey question asks for the expenses for: ''Other clinical staff, including RNs, LPNs, physicists, lab technicians, x-ray technicians, medical assistants, and other clinical personnel who cannot independently bill.'' The non-physician, health-related wage cost share for the proposed revised MEI is 4.636 percent. Together the non-health and health-related, non-physician wage costs sum to be equal to the total non-physician wage share in the proposed revised MEI of 11.885 percent.

We are proposing to disaggregate the non-physician, non-health-related wage cost weight of 7.249 percent into four occupational subcategories. The methodology is similar to that finalized in the CY 2011 PFS final rule with comment period (75 FR 73264), in that we are proposing to use 2006 Current Population Survey (CPS) data and 2006 BLS Occupational Employment Statistics (OES) data to develop cost weights for wages for non-physician, non-health-related occupational groups. We determined total annual earnings for offices of physicians using employment data from the CPS and mean annual earnings from the OES. To arrive at a distribution for these separate occupational categories (Professional & Related (P&R) workers, Managers, Clerical workers, and Service workers), we determined annual earnings for each using the Standard Occupational Classification (SOC) system. We then determined the overall share of the total for each. The occupational distribution in the proposed revised MEI as well as the distribution for the 2006-based MEI is presented in Table 15.

TABLE 15—PERCENT DISTRIBUTION OF NONPHYSICIAN PAYROLL EXPENSE BY OCCUPATIONAL GROUP: PROPOSED REVISED 2006-BASED MEI AND CURRENT 2006-BASED MEI

Current MEI (2006 = 100), finalized in the CY11 PFS final rule		Proposed MEI (2006 = 100), CY14 PFS proposed rule	
Cost Category	Current MEI06 (percent)	Revised MEI06 (percent)	Revised cost category
Non-physician compensation	19.153	16.553	Non-physician compensation.
Non-physician wages	13.752	11.885	Non-physician wages.
	.....	7.249	Non-health, non-phys. wages.
P&T	6.006	0.800	Professional and Related.
Management	1.446	1.529	Management.
Clerical	4.466	4.720	Clerical.
Services	1.834	0.200	Services.
	.....	4.636	Health related, non-phys. Wages.
Non-physician benefits	5.401	4.668	Non-physician benefits.

The health-related workers were previously included mainly in the Professional and Technical and Service Categories. These proposed changes allow for health-related workers to be proxied by a health-specific ECI rather than an ECI for more general occupations.

(b) Other Practice Expense

The remaining expenses in the MEI are categorized as Other Practice Expenses. In the current 2006-based MEI we had classified other PEs in one of the following subcategories: Office Expenses; Drugs and Supplies; and All Other Professional Expenses. For CY 2014, we are proposing to disaggregate these expenses in a way consistent with the MEI TAP's recommendations, as detailed below.

We rely on the 2006 AMA PPIS data to determine the cost share for Other Practice Expenses. These expenses are the total of office expenses, medical supplies, medical equipment, Professional Liability Insurance (PLI), and all other professional expenses.

For the proposed revised 2006-based MEI, we propose to disaggregate Other Practice Expenses into 15 detailed subcategories as shown in Table 16.

TABLE 16—REVISED COST CATEGORIES FOR OTHER PRACTICE EXPENSE

Revised cost category	Revised MEI06 (percent)
Other Practice Expense	32.581
Utilities	1.266
Miscellaneous Office Expenses	2.478
Chemicals	0.723
Paper	0.656
Rubber & Plastics	0.598
All other products	0.500
Telephone	1.501
Postage	0.898
All Other professional services	8.095
Professional, Scientific, and Tech. Svcs.	2.592
Administrative and support & waste	3.052
All Other Services	2.451
Capital	10.310
Fixed	8.957
Moveable	1.353
Professional Liability Insurance	4.295
Medical Equipment	1.978
Medical supplies	1.760

For most of these categories, we use the same method as finalized in the CY 2011 PFS final rule with comment period to estimate the cost shares. In particular, the cost shares for the following categories are derived directly from expense data reported on the 2006 AMA PPIS: PLI; Medical Equipment; and Medical Supplies. In each case, the cost shares remain the same as in the current MEI. Additionally, we continue to use the Bureau of Economic Analysis (BEA) 2002—Benchmark I/O data aged to 2006 to determine the cost weights for other expenses not collected directly from the AMA PPIS. The BEA 2002-Benchmark I/O data can be accessed at the following link: *http://www.bea.gov/industry/io_benchmark.htm#2002data.*

The derivation of the cost weight for each of the detailed categories under Other Practice Expenses is provided below.

- *Utilities:* The Utilities cost weight includes expenses classified in the fuel, oil and gas, water and sewage, and electricity industries. The proposed cost weight for utilities is 1.266 percent, the same cost share as in the current MEI.

• *Miscellaneous Office Expenses:* We are proposing to include an aggregate category of detailed office expenses that were stand-alone categories in the current 2006-based MEI. During the CY 2011 PFS proposed rule comment period, several commenters expressed confusion as to the relevance of these categories to their practice costs. The MEI TAP discussed the degree of granularity needed in both the calculation and reporting of the MEI. The MEI TAP concluded that it might be prudent to collapse some of the non-labor PE categories with other categories for presentation purposes. In particular, Recommendation 3.4 was that:

''OACT report more aggregated costs under the Office Expenses cost category. In particular, reported costs associated with Rubber and Plastics, Chemicals, All Other Products, and Paper should be combined. However, the Panel believes that OACT should maintain separately the underlying details and calculations associated with these aggregated costs when applying price proxies and calculating the overall MEI and its subcomponents.'' Based on this recommendation, we are proposing to add an aggregate category to the MEI that includes the expenses for paper, chemicals, rubber and plastics, and all other products. The cost shares for paper, chemicals, rubber and plastics, and all other products remain the same for the proposed revised MEI as in the current MEI.''

• *Telephone:* The telephone cost weight includes expenses classified in the telecommunications (accounting for the majority of the telephone expenses) and cable industries. The cost weight for Telephone services is 1.501 percent in the proposed revised MEI, the same cost share as in the current MEI.

• *Postage:* The Postage cost weight includes postal service expenses. The cost weight for Postage is 0.898 percent in the proposed revised MEI, the same cost share as in the current MEI.

• *All Other Services:* We propose to combine the All Other Services cost weight and All Other Professional Expenses into a single cost category. The proposed weight for the All Other Professional Services category is 8.095 percent, which is the sum of the current MEI weight for All Other Services (3.581 percent) and All Other Professional Expenses (4.513 percent), is more in line with the GPCI Purchased Services index as finalized in the CY2012 PFS final rule with comment period (76 FR 73085). The TAP Recommendation 3.3 was that

''OACT create a new cost category entitled Professional Services that should consist of the All Other Services cost category (and its respective weight) and the Other Professional Expenses cost category (and its respective weight). The Panel further recommends that this category be disaggregated into appropriate occupational categories consistent with the relevant price proxies.''

We propose to combine the ''Other Professional Expenses'' and ''All Other Services'' cost weights of the 2006-based MEI and further disaggregate the 8.095 percent of expenses into more detail based on the BEA I–O data, allowing for specific cost weights for services such as contract billing services, accounting, and legal services. We considered various levels of aggregation; however, in considering the level of aggregation, the available corresponding price proxies must be considered. Given the price proxies that are available from the ECI, we propose to disaggregate these expenses into three categories:

• *NAICS 54 (Professional, Scientific, and Technical Services):* The Professional, Scientific, and Technical Services sector comprises establishments that specialize in performing professional, scientific, and technical activities for others. These activities require a high degree of expertise and training. The establishments in this sector specialize according to expertise and provide these services to clients in a variety of industries, including but not limited to: legal advice and representation; accounting, and payroll services; computer services; management consulting services; and advertising services and have a 2.592 percent weight.

• *NAICS 56 (Administrative and Support and Waste Management and Remediation Services):* The Administrative and Support and Waste Management and Remediation Services sector comprises establishments performing routine support activities for the day-to-day operations of other organizations. The establishments in this sector specialize in one or more of these support activities and provide these services to clients in a variety of industries including but not limited to: office administration; temporary help services; security services; cleaning and janitorial services; and trash collection services. These services have a 3.052 percent weight.

• *All Other Services, a residual category of these expenses:* The residual All Other Services cost category is mostly comprised of expenses associated with service occupations, including but not limited to: Lab and blood specimen transport; catering and food services; collection company services; and dry cleaning services and have a 2.451 percent weight.

++ *Fixed Capital:* The Fixed Capital cost weight includes expenses for building leases and depreciation. The cost weight for Fixed Capital is 8.957 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Moveable Capital:* The Moveable Capital cost weight includes expenses for non-medical equipment including but not limited to, computer equipment and software, as well as the rental and leasing of automotive and industrial machinery equipment. The cost weight for Moveable Capital is 1.353 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Professional Liability Insurance (PLI):* The weight for PLI expense was derived from the 2006 AMA survey and was calculated as the mean PLI expense expressed as a percentage of total expenses. The cost weight for PLI is 4.295 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Medical Equipment Expenses:* The proposed weight for Medical Equipment was calculated using the 2006 AMA PPIS mean expense data. The cost weight for Medical Equipment Expenses is 1.978 percent in the proposed revised MEI, the same cost share as in the current MEI.

++ *Medical Supplies Expenses:* The proposed weight for Medical Supplies was calculated using the 2006 AMA PPIS mean expense data. The cost weight for Medical Supplies Expenses is 1.760 percent in the proposed revised MEI, the same cost share as in the current MEI.

2. Selection of Price Proxies for Use in the MEI

After developing the cost category weights for the proposed revised 2006-based MEI, we reviewed all the price proxies based on the recommendations from the MEI TAP. As was the case in the development of the current 2006-based MEI, most of the proxy measures we considered are based on BLS data and are grouped into one of the following four categories:

• *Producer Price Indices (PPIs):* PPIs measure price changes for goods sold in markets other than retail markets. These fixed-weight indexes are measures of price change at the intermediate or final stage of production. They are the preferred proxies for physician purchases as these prices appropriately reflect the product's first commercial transaction.

• *Consumer Price Indices (CPIs):* CPIs measure change in the prices of final

goods and services bought by consumers. Like the PPIs, they are fixed weight indexes. Since they may not represent the price changes faced by producers, CPIs are used if there are no appropriate PPIs or if the particular expenditure category is likely to contain purchases made at the final point of sale.

• *Employment Cost Indices (ECIs) for Wages & Salaries:* These ECIs measure the rate of change in employee wage rates per hour worked. These fixed-weight indexes are not affected by employment shifts among industries or occupations and thus, measure only the pure rate of change in wages.

• *Employment Cost Indices (ECIs) for Employee Benefits:* These ECIs measure the rate of change in employer costs of employee benefits, such as the employer's share of Social Security taxes, pension and other retirement plans, insurance benefits (life, health, disability, and accident), and paid leave. Like ECIs for wages & salaries, the ECIs for employee benefits are not affected by employment shifts among industries or occupations.

When choosing wage and price proxies for each expense category, we evaluate the strengths and weaknesses of each proxy variable using the following four criteria.

• *Relevance:* The price proxy should appropriately represent price changes for specific goods or services within the expense category. Relevance may encompass judgments about relative efficiency of the market generating the price and wage increases.

• *Reliability:* If the potential proxy demonstrates a high sampling variability, or inexplicable erratic patterns over time, its viability as an appropriate price proxy is greatly diminished. Notably, low sampling variability can conflict with relevance—since the more specifically a price variable is defined (in terms of service, commodity, or geographic area), the higher the possibility of high sampling variability. A well-established time series is also preferred.

• *Timeliness of actual published data:* For greater granularity and the need to be as timely as possible, we prefer monthly and quarterly data to annual data.

• *Public availability:* For transparency, we prefer to use data sources that are publicly available.

Below we discuss the price and wage proxies for each cost category of the proposed revised 2006-based MEI (as shown in Table 17). We will continue to use the same price proxies as those used in the 2006-based MEI except as noted below.

a. Physician Compensation (Physician's Own Time)

(1) Physician Wages and Salaries

Based on recommendations from the MEI TAP, we are proposing to use the ECI for Wages and Salaries for Professional and Related Occupations (Private Industry) (BLS series code CIU2020000120000I) to measure price growth of this category in the proposed revised 2006-based MEI. The current 2006-based MEI used Average Hourly Earnings (AHE) for Production and Non-Supervisory Employees for the Private Nonfarm Economy.

The MEI TAP had two recommendations concerning the price proxy for physician Wages and Salaries. The first recommendation from the MEI TAP was Recommendation 4.1, which was that: ''. . . OACT revise the price proxy associated with Physician Wages and Salaries from an Average Hourly Earnings concept to an Employment Cost Index concept.'' AHEs are calculated by dividing gross payrolls for wages and salaries by total hours. The AHE proxy was representative of actual changes in hourly earnings for the nonfarm business economy, including shifts in employment mix. The recommended alternative, the ECI concept, measures the rate of change in employee wage rates per hour worked. ECIs measure the pure rate of change in wages by industry and/or occupation and are not affected by shifts in employment mix across industries and occupations. The MEI TAP thought that the ECI concept better reflected physician wage trends compared to the AHE concept.

The second recommendation related to the price proxy for physician wages and salaries was Recommendation 4.2, which was that:

> CMS revise the price proxy associated with changes in Physician Wages and Salaries to use the Employment Cost Index for Wages and Salaries, Professional and Related, Private Industry. The Panel believes this change would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled 'Social Security Amendments of 1972,' which stated that the index should reflect changes in practice expenses and 'general earnings.' In the event this change would be determined not to meet the legal requirement that the index reflect ''general earnings,'' the Panel recommends replacing the current proxy with the Employment Cost Index for Wages and Salaries, All Workers, Private Industry. The Panel believed this change would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled ''Social Security Amendments of 1972,'' which stated that the index should reflect changes in practice expenses and ''general earnings.'' [1]

We agree that switching the proxy to the ECI for Wages and Salaries for Professional and Related Occupations would be consistent with the authority provided in the statute and reflect a wage trend more consistent with other professionals that receive advanced training. Additionally, we believe the ECI is a more appropriate concept than the AHE because it can isolate wage trends without being impacted by the change in the mix of employment.

(2) Physician Benefits

The MEI TAP states in Recommendation 4.3 that, ''. . . any change in the price proxy for Physician Wages and Salaries be accompanied by the selection and incorporation of a Physician Benefits price proxy that is consistent with the Physician Wages and Salaries price proxy.'' We are proposing to use the ECI for Benefits for Professional and Related Occupations (Private Industry) to measure price growth of this category in the proposed revised 2006-based MEI. The ECI for Benefits for Professional and Related Occupations is derived using BLS's Total Compensation for Professional and Related Occupations (BLS series ID CIU2010000120000I) and the relative importance of wages and salaries within total compensation. We believe this series is technically appropriate because it better reflects the benefit trends for professionals requiring advanced training. The current 2006-based MEI market basket used the ECI for Total Benefits for the Total Private Industry.

b. Practice Expense

(1) Non-Physician Employee Compensation

(a) Non-Physician Wages and Salaries

(i) Non-Physician, Non-Health-Related Wages and Salaries

• *Professional and Related:* We will continue using the ECI for Wages and Salaries for Professional and Related Occupation (Private Industry) (BLS series code CIU2020000120000I) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Management:* We will continue using the ECI for Wages and Salaries for Management, Business, and Financial (Private Industry) (BLS series code CIU2020000110000I) to measure the price growth of this cost category. This

[1] U.S. Senate, Committee on Finance, *Social Security Amendments of 1972.* ''Report of the Committee on Finance United States Senate to Accompany H.R. 1,'' September 26, 1972, p. 191.

is the same proxy used in the current 2006-based MEI.

• *Clerical:* We will continue using the ECI for Wages and Salaries for Office and Administrative Support (Private Industry) (BLS series code CIU20200002200001) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Services:* We will continue using the ECI for Wages and Salaries for Service Occupations (Private Industry) (BLS series code CIU20200003000001) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

(ii) Non-Physician, Health-Related Wages and Salaries

In Recommendation 4.4, the MEI TAP ''. . . recommend[ed] the disaggregation of the Non-Physician Compensation costs to include an additional category for health-related workers. This disaggregation would allow for health-related workers to be separated from non-health-related workers. CMS should rely directly on PPIS data to estimate the health-related non-physician compensation cost weights. The non-health, non-physician wages should be further disaggregated based on the Current Population Survey and Occupational Employment Statistics data. The new health-related cost category should be proxied by the ECI, Wages and Salaries, Hospital (NAICS 622), which has an occupational mix that is reasonably close to that in physicians' offices. The Non-Physician Benefit category should be proxied by a composite benefit index reflecting the same relative occupation weights as the non-physician wages.'' We are proposing to use the ECI for Wages and Salaries for Hospital Workers (Private Industry) (BLS series code CIU20262200000001) to measure the price growth of this cost category in the proposed revised 2006-based MEI. The ECI for Hospital workers has an occupational mix that approximates that in physicians' offices. This cost category was not broken out separately in the current 2006-based MEI.

(b) Non-Physician Benefits

We will continue using a composite ECI for non-physician employee benefits in the proposed revised 2006-based MEI. However, we are proposing to expand the number of occupations from four to five by adding detail on Non-Physician Health-Related Benefits. The weights and price proxies for the composite benefits index will be revised to reflect the addition of the new category. Table 17 lists the five ECI series and corresponding weights used to construct the proposed revised composite benefit index for non-physician employees in the proposed revised 2006-based MEI.

TABLE 17—CMS COMPOSITE PRICE INDEX FOR NON-PHYSICIAN EMPLOYEE BENEFITS IN THE PROPOSED REVISED 2006-BASED MEI

ECI Series	2006 Weight (%)
Benefits for Professional and Related Occupation (Private Industry)	7
Benefits for Management, Business, and Financial (Private Industry)	12
Benefits for Office and Administrative Support (Private Industry)	40
Benefits for Service Occupations (Private Industry)	2
Benefits for Hospital Workers (Private Industry)	39

(3) Other Practice Expense

(a) All Other Professional Services

As discussed previously, MEI TAP Recommendation 3.3 was that:

''. . . OACT create a new cost category entitled Professional Services that should consist of the All Other Services cost category (and its respective weight) and the Other Professional Expenses cost category (and its respective weight). The Panel further recommends that this category be disaggregated into appropriate occupational categories consistent with the relevant price proxies.'' We are proposing to implement this recommendation in the proposed revised 2006-based MEI using a cost category titled ''All Other Professional Services.'' Likewise, the MEI TAP stated in Recommendation 4.7 that ''. . . price changes associated with the Professional Services category be proxied by an appropriate blend of Employment Cost Indexes that reflect the types of professional services purchased by physician offices.'' We agree with this recommendation and are proposing to the use the following price proxies for each of the new occupational categories:

• *Professional, Scientific, and Technical Services:* We are proposing to use the ECI for Total Compensation for Professional, Scientific, and Technical Services (Private Industry) (BLS series code CIU20154000000001) to measure the price growth of this cost category. This cost category was not broken out separately in the current 2006-based MEI.

• *Administrative and Support Services:* We are proposing to use the ECI for Total Compensation for Administrative, Support, Waste Management, and Remediation Services (Private Industry) (BLS series code CIU20156000000001) to measure the price growth of this cost category. This cost category was not broken out separately in the current 2006-based MEI.

• *All Other Services:* We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU20100003000001) to measure the price growth of this cost category.

(b) Miscellaneous Office Expenses

• *Chemicals:* We will continue using the PPI for Other Basic Organic Chemical Manufacturing (BLS series code #PCU32519–32519) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Paper:* We will continue using the PPI for Converted Paper and Paperboard (BLS series code #WPU0915) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Rubber & Plastics:* We will continue using the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *All Other Products:* We will continue using the CPI–U for All Products less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Utilities:* We will continue using the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Telephone:* We will continue using the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Postage:* We will continue using the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

• *Fixed Capital:* In Recommendation 4.5, ''The Panel recommends using the Producer Price Index for Lessors of Nonresidential Buildings (NAICS 53112) for the MEI Fixed Capital cost category as it represents the types of

fixed capital expenses most likely faced by physicians. The Panel noted the volatility in the index, which is greater than the Consumer Price Index for Owners' Equivalent Rent of Residences. This relative volatility merits ongoing monitoring and evaluation of alternatives.'' We are proposing to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the proposed revised 2006-based MEI. The current 2006-based MEI used the CPI for Owner's Equivalent Rent. We believe the PPI for Lessors of Nonresidential Buildings is more appropriate as fixed capital expenses in physician offices should be more congruent with trends in business office space costs than residential costs.

• *Moveable Capital:* In Recommendation 4.6, the MEI TAP states that ''. . . CMS conduct research into and identify a more appropriate price proxy for Moveable Capital expenses. In particular, the Panel believes it is important that a proxy reflect price changes in the types of non-medical equipment purchased in the production of physicians' services, as well as the price changes associated with Information and Communication Technology expenses (including both hardware and software).'' We intend to continue to investigate possible data sources that could be used to proxy the physician expenses related to moveable capital in more detail. However, we will continue to use the PPI for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category in the proposed revised 2006-based MEI. This is the same proxy used in the current 2006-based MEI.

• *Professional Liability Insurance:* Unlike the other price proxies based on data from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. The MEI TAP discussed the methodology of the CMS PLI index, as well as considered alternative data sources for the PLI price proxy, including information available from BLS and through state insurance commissioners. MEI TAP Finding 4.3 states:

''The Panel finds the CMS-constructed professional liability insurance price index used to proxy changes in professional liability insurance premiums in the MEI represents the best currently available method for its intended purpose. The Panel also believes the pricing patterns of commercial carriers, as measured by the CMS PLI index, are influenced by the same driving forces as those observable in policies underwritten by physician-owned insurance entities; thus, the Panel believes the current index appropriately reflects the price changes in premiums throughout the industry.'' Given this finding, we will continue using the CMS Physician PLI index to measure the price growth of this cost category in the proposed revised 2006-based MEI. This is the same proxy used in the current 2006-based MEI.

• *Medical Equipment:* We will continue using the PPI for Medical Instruments and Equipment (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the current 2006-based MEI.

• *Medical Materials and Supplies:* We will continue using a blended index comprised of 50/50 blend of the PPI for Surgical Appliances (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). This is the same proxy used in the current 2006-based MEI.

TABLE 18—PROPOSED REVISED 2006-BASED MEI COST CATEGORIES, WEIGHTS, AND PRICE PROXIES

Cost category	2006 Weight (percent)	Price proxy
Total MEI	100.000	
Physician Compensation	50.866	
Wages and Salaries	43.641	ECI—Wages and salaries—Professional and Related (Private).
Benefits	7.225	ECI—Benefits—Professional and Related (Private).
Practice Expense	49.134	
Non-physician Compensation	16.553	
Non-physician Wages	11.885	
Non-health, non-physician wages	7.249	
Professional and Related	0.800	ECI—Wages And Salaries—Professional and Related (Private).
Management	1.529	ECI—Wages And Salaries—Mgmt., Business, and Finc. (Private).
Clerical	4.720	ECI—Wages And Salaries—Office and Admin. Support (Private).
Services	0.200	ECI—Wages And Salaries—Service Occupations (Private).
Health related, non-phys. Wages	4.636	ECI—Wages and Salaries—Hospital (Private).
Non-physician Benefits	4.668	Composite Benefit Index.
Other Practice Expense	32.581	
Miscellaneous Office Expenses	2.478	
Chemicals	0.723	PPI—Other Basic Organic Chemical Manufacturing.
Paper	0.656	PPI—Converted Paper and Paperboard.
Rubber and Plastics	0.598	PPI—Rubber and Plastic Products.
All other products	0.500	CPI—All Items Less Food And Energy.
Telephone	1.501	CPI—Telephone.
Postage	0.898	CPI—Postage.
All Other Professional Services	8.095	
Prof., Scientific, and Tech. Svcs	2.592	ECI—Compensation—Prof., Scientific, and Technical (Private).
Admin. and Support Services	3.052	ECI—Compensation—Admin., Support, Waste Mgmt. (Private).
All Other Services	2.451	ECI—Compensation—Service Occupations (Private).
Capital:		
Fixed Capital	8.957	PPI—Lessors of Nonresidential Buildings.
Moveable Capital	1.353	PPI—Machinery and Equipment.
Professional Liability Insurance	4.295	CMS—Professional Liability Phys. Prem. Survey.
Medical Equipment	1.978	PPI—Medical Instruments and Equipment.
Medical Supplies	1.760	Composite—PPI Surgical Appliances & CPI–U Medical Supplies.

3. Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) multifactor productivity that were applied to the entire index. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of economy-wide private nonfarm business labor productivity.

The MEI TAP was asked to review this approach. In Finding 5.1, ''[t]he Panel reviewed the basis for the current economy-wide multifactor productivity adjustment (Private Nonfarm Business Multifactor Productivity) in the MEI and finds such an adjustment continues to be appropriate. This adjustment prevents 'double counting' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices.''

Based on the MEI TAP's finding, we will continue to use the current method for adjusting the full MEI for multifactor productivity in the proposed revised 2006-based MEI. As described in the CY 2003 PFS final rule with comment period, we believe this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). We believe that using the 10-year moving average percent change in economy-wide multifactor productivity is appropriate for deriving a stable measure that helps alleviate the influence that the peak (or a trough) of a business cycle may have on the measure. The adjustment will be based on the latest available historical economy-wide nonfarm business multifactor productivity data as measured and published by BLS.

4. Results of Proposed Revisions on the MEI Update

Table 19 shows the average calendar year percent change from CY 2005 to CY 2014 for both the proposed revised 2006-based MEI and the current 2006-based MEI. The average annual percent change in the proposed revised 2006-based MEI is 0.1 percent lower than the current 2006-based MEI over the 2005–2013 period. On an annual basis over this period, the differences vary by up to plus or minus 0.7 percentage points. In the two most recent years (CY 2012 and CY 2013), the annual percent change in the proposed revised 2006-based MEI was within 0.1 percentage point of the percent change in the current 2006-based MEI. The majority of these differences over the historical period can be attributed to the revised price proxy for physician wages and salaries and benefits and the revised price proxy for fixed capital.

TABLE 19—ANNUAL PERCENT CHANGE IN THE PROPOSED REVISED 2006-BASED MEI, NOT INCLUDING PRODUCTIVITY ADJUSTMENT AND THE CURRENT 2006-BASED MEI, NOT INCLUDING PRODUCTIVITY ADJUSTMENT *

Update year	Proposed revised 2006-based MEI excl. MFP	Current 2006-based MEI, excl. MFP
CY 2005	3.8	3.1
CY 2006	4.0	3.3
CY 2007	3.2	3.2
CY 2008	3.2	3.4
CY 2009	2.9	3.1
CY 2010	2.4	2.8
CY 2011	0.9	1.6
CY 2012	1.7	1.8
CY 2013	1.7	1.8
Avg. Change for CYs 2005–2013	2.6	2.7

* Update year based on historical data through the second quarter of the prior calendar year. For example, the 2013 update is based on historical data through the second quarter 2012, prior to MFP adjustment.

As shown in Table 20, the projection of the proposed revised 2006-based MEI for the CY 2014 PFS proposed rule is an increase of 0.7 percent, 0.1 percentage point lower than the projected increase using the current 2006-based MEI. In the CY 2014 PFS final rule with comment period, we will incorporate historical data through the second quarter of 2013, and therefore, the current estimated increase of 0.7 percent for 2014 may differ in the final rule.

TABLE 20—PROJECTED ANNUAL PERCENT CHANGE IN THE CY 2014 PROPOSED REVISED 2006-BASED MEI AND THE CURRENT 2006-BASED MEI *

Update year	Proposed revised 2006-based MEI	Current 2006-based MEI
CY 2014	0.7	0.8

* Based on the 2nd quarter 2013 forecast from IHS Global Insight, with historical data through the 1st quarter 2013.

For the productivity adjustment, the 10-year moving average percent change adjustment for CY 2014 is 0.9 percent, which is based on the most historical data available from BLS at the time of the proposed rule. If more recent historical data of MFP is available at the time of the final rule, we will incorporate it into the final MEI update.

TABLE 21—FORECASTED ANNUAL PERCENT CHANGE IN THE PROPOSED REVISED MEI FOR CY 2014

[All Categories]

Revised cost category	Revised price proxy	Revised cost weight (percent)	CY14 update (percent)
MEI		100.000	0.7
MFP	*10-yr moving average of* Private Nonfarm Business Multifactor Productivity.	N/A	0.9
MEI without productivity adjustment		100.000	1.6

TABLE 21—FORECASTED ANNUAL PERCENT CHANGE IN THE PROPOSED REVISED MEI FOR CY 2014—Continued

[All Categories]

Revised cost category	Revised price proxy	Revised cost weight (percent)	CY14 update (percent)
Physician Compensation		50.866	2.0
Wages and Salaries	ECI—Wages and salaries—Professional and Related (private).	43.641	1.9
Benefits	ECI—Benefits—Professional and Related (private)	7.225	2.2
Practice Expense		49.134	1.3
Non-physician compensation		16.553	1.7
Non-physician wages		11.885	1.7
Non-health, non-physician wages		7.249	1.8
Professional & Related	ECI—Wages And Salaries—Professional and Related (Private).	0.800	1.9
Management	ECI—Wages And Salaries—Managers & Administrators (Private).	1.529	1.7
Clerical	ECI—Wages And Salaries—Admin Support incl Clerical (Private).	4.720	1.8
Services	ECI—Wages And Salaries—Service Occupations (Private).	0.200	1.5
Health related, non-physician wages	ECI—Wages and Salaries—Hospital (civilian)	4.636	1.5
Non-physician benefits	Composite Benefit Index	4.668	1.7
Other Practice Expense		32.581	1.1
Utilities	CPI Fuels and Utilities	1.266	0.7
Miscellaneous Office Expenses		2.478	0.3
Chemicals	Other Basic Organic Chemical Manufacturing PPI325190.	0.723	−1.2
Paper	PPI for converted paper	0.656	1.1
Rubber & Plastics	PPI for rubber and plastics	0.598	0.3
All other products	CPI—All Items Less Food And Energy	0.500	1.9
Telephone	CPI for Telephone	1.501	0.1
Postage	CPI for Postage	0.898	4.9
All Other Professional Services		8.095	1.7
Professional, Scientific, and Tech. Svcs	ECI—Compensation: Prof. scientific, tech	2.592	1.7
Administrative and support & waste	ECI—Compensation Administrative	3.052	1.8
All Other Services	ECI Compensation: Services Occupations	2.451	1.6
Capital		10.310	0.5
Fixed	PPI for Lessors of nonresidential buildings	8.957	0.5
Moveable	PPI for Machinery and Equipment	1.353	0.8
Professional Liability Insurance	CMS—Prof. Liability. Phys. Prem. Survey	4.295	0.9
Medical Equipment	PPI—Med. Inst. & Equip	1.978	1.4
Medical supplies	Composite—PPI Surg. Appl. & CPIU Med. Supplies. (CY2006).	1.760	1.0

* Based on the 2nd quarter 2013 forecast from IHS Global Insight, with historical data through the 1st quarter 2013.

E. 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 resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice (MP)). The 89 total PFS localities are discussed in section II.E.3. of this proposed rule. While requiring 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 at the end of 2012. Section 602 of the ATRA amended the statute to extend the 1.0 floor for the work GPCIs through CY 2013 (that is, for services furnished no later than December 31, 2013).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that ''if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made.'' Therefore, since the previous GPCI update was implemented in CY 2011 and CY 2012, we are proposing to phase in ½ of the latest GPCI adjustment in CY 2014.

We have completed a review of the GPCIs and are proposing new GPCIs, as well as a revision to the cost share weights that correspond to all three GPCIs in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service 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 noted above, section 602 of the ATRA extended the 1.0 work GPCI floor only through December 31, 2013. Therefore, the proposed CY 2014 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. However, 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 2014. See Addenda D and E to this proposed rule for the proposed CY 2014 GPCIs and summarized GAFs available on the CMS Web site under the supporting documents section of the CY 2014 PFS proposed rule located at *http://www.cms.gov/PhysicianFeeSched/*.

2. GPCI Update

The proposed updated GPCI values were calculated by a contractor to CMS. There are three GPCIs (work, PE, and MP), and all GPCIs are calculated through comparison to a national average for each type. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below. Additional information on the CY 2014 GPCI update may be found in our contractor's draft report, ''*Draft 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 2014 PFS proposed rule located at *http://www.cms.gov/PhysicianFeeSched/*.

a. Work GPCIs

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

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

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

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES continues to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed in section II.E.2.b the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs.

We note that the Medicare Payment Advisory Commission (MedPAC) was required by section 3004 of the MCTRJCA to submit a report to the Congress by June 15, 2013 that assesses whether any adjustment under section 1848 of the Act to distinguish the difference in work effort by geographic area is appropriate and, if so, what that level should be and where it should be applied. In the report, MedPAC was required to also assess the impact of the work geographic adjustment under the Act, including the extent to which the floor on such adjustment impacts access to care. We did not have sufficient time to review this report, which was issued on June 14, 2013 for this proposed rule. We look forward to reviewing the MedPAC report and its recommendations with respect to the work GPCI.

b. Practice Expense GPCIs

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

For the previous update to the GPCIs (implemented in CY 2011 and CY 2012) we used 2006 through 2008 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed in section II.E.2.a., because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS

OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data for purposes of calculating the employee wage component and purchased service index of the PE GPCI.

Office Rent Index Discussion

Since the inception of the PFS, we have used residential rent data (primarily the two-bedroom residential apartment rent data produced by the Department of Housing and Urban Development (HUD) at the 50th percentile) as the proxy to measure the relative cost difference in physician office rents. As discussed in the CY 2012 PFS final rule with comment period (76 FR 73084), we had concerns with the continued use of the HUD rental data because the data were not updated frequently and the Census ''long form,'' which was used to collect the necessary base year rents for the HUD Fair Market Rent (FMR) data, was discontinued in CY 2010 and would no longer be available for future updates. Therefore, we examined the suitability of using 3-year (2006–2008) American Community Survey (ACS) rental data as a proxy for physician office rents to replace the HUD data. We determined that the ACS is one of the largest nationally representative surveys of household rents in the United States conducted annually by the U.S. Census Bureau, sampling approximately 3 million addresses with a recent response rate above 97 percent, and that it reports rental information for residences at the county level. Given that the ACS rental data provided a sufficient degree of reliability, is updated annually, and was expected to be available for future updates, we used the 2006 through 2008 ACS 3-year residential rent data as a replacement for the HUD data to create the office rent index for the CY 2012 PFS final rule with comment (76 FR 73084). For all the same reasons that we used the ACS data for the last GPCI update, we propose to use the most recent 3-year ACS residential rent data (2008 through 2010) to calculate the office rent component of the PE GPCI. We note that when responding to the ACS survey, individuals also report whether utilities are included in their rent. Thus, the cost of utilities cannot be separated from ''gross rents'' since some individuals monthly rent also covers the cost of utilities. As discussed in section II.E.2.d. we combined the cost weights for fixed capital and utilities when assigning a proposed weight to the office rent component of the PE GPCI.

For many years, we have received requests from physicians and their representatives to use commercial rent data instead of residential rent data as a proxy to measure the relative cost differences in physician office rent. Additionally, in a report entitled ''*Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy,*'' prepared for CMS under contract and released on September 28, 2011, the Institute of Medicine recommended that ''a new source of data should be developed to determine the variation in the price of commercial office rent per square foot.'' The Institute of Medicine report did not identify any new data source and did not suggest how a new source of data might be developed. Because we could not identify a reliable commercial rental data source that is available on a national basis and includes data for non-metropolitan areas, we continued to use residential rent data for the CY 2012 GPCI update.

For the CY 2014 GPCI update, we continued our efforts to identify a reliable source of commercial rent data that could be used in calculating the rent index. We could not identify a nationally representative commercial rent data source that is available in the public sector. However, we identified a proprietary commercial rent data source that has potential for use in calculating the office rent indices in future years. To that end, we are attempting to negotiate an agreement with the proprietor to use the data for purposes of calculating the office rent component of the PE GPCI.

One of the challenges of using a proprietary data source is our ability to make information available to the public. When using government data, we are able to release all data for public consideration. However, when using a proprietary data source, it is likely that restrictions will be imposed on its use and our ability to disclose data. In such a situation, those wishing to replicate our calculations based on detailed data would also need to purchase the underlying proprietary data. We also believe that, generally speaking, a proprietary ''for profit'' data source is more susceptible to periodic changes in the criteria used for data collection, including possible changes in the data collected, the frequency at which the data is updated, changes in ownership, and the potential for termination of the survey vehicle entirely as changes are made to address economic pressures or opportunities. As such, we cannot predict that a given proprietary data source will be available in the format needed to develop office rent indices in the future. Since we have not identified a nationally representative commercial rent data source that is available in the public sector, we believe it would be necessary to use a proprietary data source for commercial office rent data. That is, in the absence of using a proprietary data source, it is unlikely that we would be able to use commercial rent data to calculate the office rent index component of the PE GPCI. Therefore, we request comments on the potential future use of a proprietary commercial rent data source as well as whether there is a source for these data that is not proprietary.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). For the CY 2011 GPCI update (sixth update) we used 2006 and 2007 malpractice premium data (75 FR 73256). The proposed CY 2014 MP GPCI update reflects 2011 and 2012 premium data.

Additionally, for the past several GPCI updates, we were not able to collect MP premium data from insurer rate filings for the Puerto Rico payment locality. For the CY 2014 (seventh) GPCI update, we worked directly with the Puerto Rico Insurance Commissioner and Institute of Statistics to obtain data on MP insurance premiums that were used to calculate an updated MP GPCI for Puerto Rico. Using updated MP premium data would result in a 17 percent increase in MP GPCI for the Puerto Rico payment locality under the proposed fully phased-in seventh GPCI update, which would be effective CY 2015.

d. GPCI Cost Share Weights

To determine the cost share weights for the proposed CY 2014 GPCIs, we used the weights we propose to use for the CY 2014 value for the revised 2006-based Medicare Economic Index (MEI) as discussed in section II.D. of this proposed rule. As discussed in detail in that section, the MEI was rebased and revised in the CY 2011 PFS final rule with comment period (75 FR 73262 through 73277) to reflect the weighted-average annual price change for various inputs needed to provide physicians' services. We have historically updated the GPCI cost share weights to make them consistent with the most recent

update to the MEI, and propose to do so again for CY 2014. We would note that consistent with this approach in the CY 2011 proposed rule, the last time the MEI was revised, we proposed to update the GPCI cost share weights to reflect these revisions to the MEI. However, in response to public comments we did not finalize the proposal in the CY 2011 PFS final rule with comment period (75 FR 73258 and 73260), so that we could explore public comments received suggesting the reallocation of labor related costs from the medical equipment, supplies and miscellaneous component to the employee compensation component and comments received on the cost share weight for the rent index of the PE GPCI as well as to continue our analysis of the cost share weights attributed to the PE GPCIs as required by section 1848(e)(1)(H)(iv) of the Act.

In the CY 2012 PFS final rule (76 FR 73085 through 73086) we addressed commenter concerns regarding the inclusion of the cost share weight assigned to utilities within the office rent component of the PE GPCI and to geographically adjust wage related industries contained within the medical equipment, supplies and miscellaneous component of the PE GPCI. As a result, to accurately capture the utility measurement present in the ACS two bedroom gross rent data, the cost share weight for utilities was combined with the fixed capital portion to form the office rent index. Additionally, we developed a purchased service index to geographically adjust the labor-related components of the ''All Other Services'' and ''Other Professional Expenses'' categories of the 2006-based MEI market basket. Upon completing our analysis of the GPCI cost share weights (as required by the Act) and addressing commenters' concerns regarding the office rent and labor related industries previously contained in the medical equipment, supplies and other miscellaneous components of the PE GCPI, we updated the GPCI cost share weights consistent with the weights established in the 2006-based MEI in the CY 2012 PFS final rule (76 FR 73086).

The proposed revised 2006-based MEI cost share weights reflect our actuaries' best estimate of the weights associated with each of the various inputs needed to provide physicians' services. Use of the current MEI cost share weights also provides consistency across the PFS in the use of this data. Given that we have addressed previous commenters concerns about the allocation of labor related costs (as discussed earlier in this section) and that we have completed our analysis of the GPCI cost share weights (as required by the Act) we believe it is appropriate to propose to adopt the weights we are proposing to use for the revised 2006-based MEI as the GPCI cost share weights for CY 2014.

As a result, the cost share weight for the work GPCI (as a percentage of the total) in this proposal is changed from 48.266 percent to 50.866 percent, and the cost share weight for the PE GPCI is revised from 47.439 percent to 44.839 percent with a change in the employee compensation component from 19.153 to 16.553 percentage points. The cost share weights for the office rent component (10.223 percent), purchased services component (8.095 percent), and the medical equipment, supplies, and other miscellaneous expenses component (9.968 percent) of the PE GPCI and the cost share weight for the MP GPCI (4.295 percent) remains unchanged. A discussion of the specific MEI cost centers and the respective weights used to calculate each GPCI component (and subcomponent) is provided below.

(1) Work GPCIs

We propose to adopt the proposed revised weight of 50.866 for the physician compensation cost category as the proposed work GPCI cost share weight.

(2) Practice Expense GPCIs

For the cost share weight for the PE GPCIs, we used the revised 2006-based MEI proposed weight for the PE category of 49.134 percent minus the PLI category weight of 4.295 percent (because the relative costs differences in malpractice expenses are measured by its own GPCI). Therefore, the proposed cost share weight for the PE GPCIs is 44.839 percent.

(a) Employee Compensation

For the employee compensation portion of the PE GPCIs, we used the proposed non-physician employee compensation category weight of 16.553 percent reflected in the revised 2006-based MEI.

(b) Office Rent

We set the PE GPCI office rent portion at 10.223 percent which includes the proposed revised 2006-based MEI cost weights for fixed capital (reflecting the expenses for rent, depreciation on medical buildings and mortgage interest) and utilities. As discussed previously in this section, we propose to use 2008–2010 ACS rental data as the proxy for physician office rent. As mentioned previously, these data represent a gross rent amount and include data on utility expenditures. Since it is not possible to separate the utilities component of rent for all ACS survey respondents, we combined these two components to calculate office rent values that were used to calculate the office rent index component of the proposed PE GPCI. For purposes of consistency, we combined those two cost categories when assigning a proposed weight to the office rent component.

(c) Purchased Services

As discussed in section II.D. of this proposed rule, to be consistent with the purchased services index, we are proposing to combine the current MEI cost share weights for ''All Other Services'' and ''Other Professional Expenses'' into a component called ''All Other Professional Services.'' The proposed weight for ''All Other Professional Services'' is 8.095. As noted in the CY 2012 PFS final rule with comment period (76 FR 73084), we only adjust for locality cost differences of the labor-related share of the purchased services index. We determined that only 5.011 percentage points of the total 8.095 proposed weight are labor-related and, thus, would be adjusted for locality cost differences (5.011 adjusted purchased service + 3.084 non-adjusted purchased services = 8.095 total cost share weight). Therefore, only 62 percent (5.011/8.095) of the purchased service index is adjusted for geographic cost differences while the remaining 38 percent (3.084/8.095) of the purchased service index is not adjusted for geographic variation.

(d) Equipment, Supplies, and Other Miscellaneous Expenses

To calculate the medical equipment, supplies, and other miscellaneous expenses component, we removed PLI (4.295 percentage points), non-physician employee compensation (16.553 percentage points), fixed capital/utilities (10.223 percentage points), and purchased services (8.095 percentage points) from the total proposed PE category weight (44.839 percent). Therefore, the proposed cost share weight for the medical equipment, supplies, and other miscellaneous expenses component is 9.968 percent (44.839 − (4.295 + 16.553 + 10.223 + 8.095) = 9.968). As explained above, because we believe there is a national market for these items, costs that fall within this component of the PE GPCI are not adjusted for geographic variation.

(3) Malpractice GPCIs

We propose to use the PLI weight of 4.295 percent for the MP GPCI cost

share weight. The proposed GPCI cost share weights for CY 2014 are displayed in Table 22.

TABLE 22—PROPOSED COST SHARE WEIGHTS FOR CY 2014 GPCI UPDATE

Expense category	Current cost share weight (percent)	Proposed CY 2014 cost share weight (percent)
Work	48.266	50.866
Practice Expense	47.439	44.839
—Employee Compensation	19.153	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be frontier States. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System final rule (75 FR 50160 through 50161). There are no changes in the States identified as ''Frontier States'' for the CY 2014 proposed rule. The qualifying States are reflected in Table 23. In accordance with statute, we will apply a 1.0 PE GPCI floor for these States in CY 2014.

TABLE 23—FRONTIER STATES UNDER SECTION 1848(E)(1)(I) OF THE ACT

[As added by section 10324(c) of the Affordable Care Act]

State	Total counties	Frontier counties	Percent frontier counties (relative to counties in the State) (percent)
Montana	56	45	80
Wyoming	23	17	74
North Dakota	53	36	68
Nevada	17	11	65
South Dakota	66	34	52

f. Proposed GPCI Update

As explained above in the background section, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2014 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on the CMS Web site under the supporting documents section of the CY 2014 PFS proposed rule Web page at *http://www.cms.gov/PhysicianFeeSched/*.

3. Payment Locality Discussion

a. Background

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

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

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

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

configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), we require that changes to the PFS locality structure be done in a budget neutral manner within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. In recent years, we have also considered more comprehensive changes to locality configuration. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*www.cms.gov/physicianfeesched/downloads/ReviewOfAltGPCIs.pdf*). The alternative locality configurations in the report are described below.

- *Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration:* CBSAs are a combination of Office of Management and Budget (OMB's) Metropolitan Statistical Areas (MSAs) and Micropolitan Statistical Areas. Under this option, MSAs would be considered as urban CBSAs. Micropolitan Statistical Areas (as defined by OMB) and rural areas would be considered as non-urban (rest of state) CBSAs. This approach would be consistent with the areas used in the Inpatient Prospective Payment System (IPPS) pre-reclassification wage index, which is the hospital wage index for a geographic area (CBSA or non-CBSA) calculated from submitted hospital cost report data before statutory adjustments reconfigure, or ''reclassify'' a hospital to an area other than its geographic location, to adjust payments for differences in local resource costs in other Medicare payment systems. Based on data used in the 2008 locality report, this option would increase the number of PFS localities from 89 to 439.
- *Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties):* Under this approach, higher cost counties are removed from their existing locality structure, and they would each be placed into their own locality. This option would increase the number of PFS localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties.
- *Option 3: Separate MSAs from Statewide Localities (Separate MSAs):* This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of PFS localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs.
- *Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers):* This option creates tiers of counties (within each state) that may or may not be contiguous but share similar practice costs. This option would increase the number of PFS localities from 89 to 140, using a 5 percent GAF differential to group similar counties into statewide tiers.

For a detailed discussion of the public comments on the contractor's 2008 draft report detailing four different locality configurations, we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757). There was no public consensus on the options, although a number of commenters expressed support for Option 3 (separate MSAs from statewide localities) because the commenters believed this alternative would improve payment accuracy and could mitigate potential reductions to rural areas compared to Option 1 (CMS CBSAs).

In response to some public comments regarding the third of the four locality options, we had our contractor conduct an analysis of the impacts that would result from the application of Option 3. Those results were displayed in the final locality report released in 2011. The final report, entitled ''*Review of Alternative GPCI Payment Locality Structures—Final Report,*'' may be accessed directly from the CMS Web site at *www.cms.gov/PhysicianFee Sched/downloads/Alt_GPCI_Payment_Locality_Structures_Review.pdf.*

Moreover, at our request, the Institute of Medicine conducted a comprehensive empirical study of the Medicare GAFs established under sections 1848(e) (PFS GPCI) and 1886(d)(3)(E) (IPPS hospital wage index) of the Act. These adjustments are designed to ensure Medicare payments reflect differences in input costs across geographic areas. The first of the Institute of Medicine's two reports entitled, ''*Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy*'' recommended that the same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Further, the Institute of Medicine recommended that MSAs and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.

Under the Institute of Medicine's recommendations, MSAs would be considered as urban CBSAs. Micropolitan Areas (as defined by the OMB) and rural areas would be considered as non-urban (rest of State) CBSAs. This approach would be consistent with the areas used in the IPPS pre-reclassification wage index to make geographic payment adjustments in other Medicare payment systems. For more information on the Institute of Medicine's recommendations on the PFS locality structure, see the CY 2013 PFS final rule with comment period (77 FR 68949). We also provided our technical analyses of the Institute of Medicine Phase I recommendations in a report released on the PFS Web site at *www.cms.gov/PhysicianFeeSched.*

Additionally, the Phase I report can be accessed on the Institute of Medicine's Web site at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.*

b. Institute of Medicine Phase II Report Discussion

The Institute of Medicine's second report, entitled ''*Geographic Adjustment in Medicare Payment—Phase II: Implications for Access, Quality, and Efficiency*'' was released July 17, 2012 and can be accessed on the Institute of Medicine's Web site at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.*

The Phase II report evaluated the effects of geographic adjustment factors (hospital wage index and GPCIs) on the distribution of the health care workforce, quality of care, population health, and the ability to provide efficient, high value care. The Institute of Medicine's Phase II report also included an analysis of the impacts of implementing its recommendations for accuracy in geographic adjustments which include a CBSA-based locality structure under the PFS. The Institute of Medicine analysis found that adopting a CBSA-based locality structure under the PFS creates large changes in county GAF values; for example, approximately half of all US counties would experience a payment reduction. The Institute of Medicine also found that GPCIs calculated under a CBSA-based locality structure would result in lower GAFs in rural areas (relative to the national average) because the GPCI values for rural areas would no longer include metropolitan practice costs within the current ''rest-of-state'' or ''statewide'' localities.

(1) Institute of Medicine Phase II Report Recommendations

The Institute of Medicine developed recommendations for improving access to and quality of medical care. The

recommendations included in the Institute of Medicine's Phase II report are summarized as follows:

- *Recommendation 1:* The Medicare program should develop and apply policies that promote access to primary care services in geographic areas where Medicare beneficiaries experience persistent access problems.
- *Recommendation 2:* The Medicare program should pay for services that improve access to primary and specialty care for beneficiaries in medically underserved urban and rural areas, particularly telehealth technologies.
- *Recommendation 3:* To promote access to appropriate and efficient primary care services, the Medicare program should support policies that would allow all qualified practitioners to practice to the full extent of their educational preparation.
- *Recommendation 4:* The Medicare program should reexamine its policies that provide location-based adjustments for specific groups of hospitals, and modify or discontinue them based on their effectiveness in ensuring adequate access to appropriate care.
- *Recommendation 5:* Congress should fund an independent ongoing entity, such as the National Health Care Workforce Commission, to support data collection, research, evaluations, and strategy development, and make actionable recommendations about workforce distribution, supply, and scope of practice.
- *Recommendation 6:* Federal support should facilitate independent external evaluations of ongoing workforce programs intended to provide access to adequate health services for underserved populations and Medicare beneficiaries. These programs include the National Health Services Corps, Title VII and VIII programs under the Public Health Service Act, and related programs intended to achieve these goals.

(2) Institute of Medicine Phase II Report Conclusions

The Institute of Medicine committee concluded that geographic payment adjustments under the PFS are not a strong determinant of access problems and not an appropriate mechanism for improving the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Specifically, the Institute of Medicine committee stated ''that there are wide discrepancies in access to and quality of care across geographic areas particularly for racial and ethnic minorities. However, the variations do not appear to be strongly related to differences in or potential changes to fee for service payment'' (Page. 6). The committee also concluded ''that Medicare beneficiaries in some geographic pockets face persistent access and quality problems, and many of these pockets are in medically underserved rural and inner-city areas. However, geographic adjustment of Medicare payment is not an appropriate approach for addressing problems in the supply and distribution of the health care workforce. The geographic variations in the distribution of physicians, nurses and physician assistants, and local shortages that create access problems for beneficiaries should be addressed through other means'' (Page. 7). Moreover, the committee concluded that ''geographic [payment] adjustment is not an appropriate tool for achieving policy goals such as improving quality of expanding the pool of providers available to see Medicare beneficiaries'' (Page. 9).

(3) CMS Summary Response to Institute of Medicine Phase II Report

The Institute of Medicine's Phase II report recommendations are broad in scope, do not propose specific recommendations for making changes to the GPCIs or PFS locality structure, or are beyond the statutory authority of CMS.

We agree with the Institute of Medicine's assessment that many counties would experience a payment reduction and that large payment shifts would occur as a result of implementing a CBSA-based locality configuration under the PFS. Based on our contractor's analysis, there would be significant redistributive impacts if we were to implement a policy that would reconfigure the PFS localities based on the Institute of Medicine's CBSA-based locality recommendation. Many rural areas would see substantial decreases in their corresponding GAF and GPCI values as higher cost counties are removed from current ''rest of state'' payment areas. Conversely, many urban areas, especially those areas that are currently designated as ''rest of state'' but are located within higher cost MSAs, would experience increases in their applicable GPCIs and GAFs. That is, given that urban and rural areas would no longer be grouped together (for example, as in the current 34 statewide localities), many rural areas would see a reduction in payment under a CBSA-based locality configuration.

As noted earlier in this section, we are assessing a variety of approaches to changing the locality structure under the PFS and will continue to study options for revising the locality structure. However, to fully assess the implications of proposing a nationwide locality reconfiguration under the PFS, we must also assess and analyze the operational changes necessary to implement a revised locality structure. Given that all options under consideration (including the Institute of Medicine's CBSA-based approach) would expand the number of current localities and result in payment reductions to primarily rural areas, presumably any nationwide locality reconfiguration could potentially be transitioned over a number of years (to phase-in the impact of payment reductions gradually, from year to year, instead of all at once). As such, transitioning from the current locality structure to a nationwide reconfigured locality structure would present operational and administrative challenges that need to be identified and addressed. Therefore, we have begun to assess the broad operational changes that would be involved in implementing a nationwide locality reconfiguration under the PFS. Accordingly, we believe that it would be premature to make any statements about potential changes we would consider making to the PFS localities at this time. Any changes to PFS fee schedule areas would be made through future notice and comment rulemaking.

In the event that we develop a specific proposal for changing the locality configuration during future rulemaking, we would provide detailed analysis on the impact of the changes for physicians in each county. We would also provide opportunities for public input.

F. Medicare Telehealth Services for the Physician Fee Schedule

1. Billing and Payment for Telehealth Services

a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA

specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment that would have been made to the consultant for the service furnished. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (BIPA) (Pub. L. 106–554) added section 1834(m) to the Act, which significantly expanded Medicare telehealth services. 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 delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

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 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. Under the BIPA, originating sites were limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, a critical access hospital (CAH), a rural health clinic (RHC), a federally qualified health center (FQHC) and a hospital (as defined in section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) expanded the list of telehealth originating sites to include a hospital-based renal dialysis center, a skilled nursing facility (SNF), and a community mental health center (CMHC). To serve as a telehealth originating site, a site must also be located in an area designated as a rural HPSA, in a county that is not in a metropolitan statistical area (MSA), or must be an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be with a telepresenter at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in a qualifying originating site. An originating site is 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. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner;
- Hospitals;
- CAHs;
- RHCs;
- FQHCs;
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites);
- SNFs;
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations;
- Follow-up inpatient consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;
- Psychiatric diagnostic interview examination;
- End-stage renal disease (ESRD) related services;
- Individual and group medical nutrition therapy (MNT);
- Neurobehavioral status exam;
- Individual and group health and behavior assessment and intervention (HBAI);
- Subsequent hospital care;
- Subsequent nursing facility care;
- Individual and group kidney disease education (KDE);
- Individual and group diabetes self-management training (DSMT);
- Smoking cessation services;
- Alcohol and/or substance abuse and brief intervention services;
- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse;
- Screening for depression in adults;
- Screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs;
- Intensive behavioral therapy for cardiovascular disease; and
- Behavioral counseling for obesity.

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under state law to furnish the service via a telecommunications system:

- Physician;
- Physician assistant (PA);
- Nurse practitioner (NP);
- Clinical nurse specialist (CNS);
- Nurse-midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian or nutrition professional.

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. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service, appended with the –GT (via interactive audio and video telecommunications system) or –GQ (via asynchronous telecommunications system) modifier. By reporting the –GT or –GQ modifier with a covered

telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology 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 (that is, without the –GT or –GQ modifier appended).

c. Geographic Criteria for Originating Site Eligibility

Section 1834(m)(4)(C)(i)(I)–(III) of the Act specifies three criteria for the location of eligible telehealth originating sites. One of these is for entities participating in federal telemedicine demonstration projects as of December 31, 2000, and the other two are geographic. One of the geographic criteria is that the site is located in a county that is not in an MSA and the other is that the site is located in an area that is designated as a rural HPSA under section 332(a)(1)(A) of the Public Health Service Act (PHSA) (42 U.S.C. 254e(a)(1)(A)). Section 332(a)(1)(A) of the PHSA provides for the designation of various types of HPSAs, but does not provide for ''rural'' HPSAs. In the absence of guidance in the PHSA, CMS has in the past interpreted the term ''rural'' under section 1834(m)(4)(C)(i)(I) to mean an area that is not located in an MSA. As such, the current geographic criteria for telehealth originating sites limits eligible sites to those that are not in an MSA.

To determine rural designations with more precision, HHS and CMS have sometimes used methods that do not rely solely on MSA designations. For example, the Office of Rural Health Policy (ORHP) uses the Rural Urban Commuting Areas (RUCAs) to determine rural areas within MSAs. RUCAs are a census tract-based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work commuting information to characterize all of the nation's census tracts regarding their rural and urban status and relationships. They were developed under a collaborative project between ORHP, the U.S. Department of Agriculture's Economic Research Service (ERS), and the WWAMI Rural Health Research Center (RHRC). A more comprehensive description is available at the USDA ERS Web site at: *www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation.aspx#.UcsKfZwzZKE*. The RUCA classification scheme contains 10 primary and 30 secondary codes. The primary code numbers (1 through 10) refer to the primary, or single largest, commuting share. Census tracts with RUCA codes of 4 through 10 refer to areas with a primary commuting share outside of a metropolitan area. In addition to counties that are not in an MSA, ORHP considers some census tracts in MSA counties to be rural. Specifically, census tracts with RUCA codes 4 through 10 are considered to be rural, as well as census tracts with RUCA codes 2 and 3 that are also at least 400 square miles and have a population density of less than 35 people per square mile.

We are proposing to modify our regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by ORHP. We believe that defining ''rural'' to include geographic areas located in rural census tracts within MSAs would allow for the appropriate inclusion of additional HPSAs as areas for telehealth originating sites. We also believe that adopting the more precise definition of ''rural'' for this purpose would expand access to health care services for Medicare beneficiaries located in rural areas.

We are also proposing to change 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. Absent this proposed change, the status of a geographic area's eligibility for telehealth originating site payment is effective at the same time as the effective date for changes in designations that are made outside of CMS. This proposed change would reduce the likelihood that mid-year changes to geographic designations would result in sudden disruptions to beneficiaries' access to services, unexpected changes in eligibility for established telehealth originating sites and avoid the operational difficulties associated with administering with mid-year Medicare telehealth payment changes. We are proposing to establish geographic eligibility for Medicare telehealth originating sites for each calendar year based upon the status of the area as of December 31st of the prior calendar year. Accordingly, we are proposing to revise our regulations at § 410.78(b)(4) to conform with both of these proposed policies.

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 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. 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 delivered 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 delivering 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.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: Individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and skilled nursing facilities (SNFs); subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT (with a minimum of 1 hour of in-person instruction to ensure effective injection training), smoking cessation services; alcohol and/or substance abuse and brief intervention services; screening and behavioral counseling interventions in primary care to reduce alcohol misuse; screening for depression in adults; screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs; intensive behavioral therapy for cardiovascular disease; and behavioral counseling for obesity.

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, requests submitted before the end of CY 2013 will be considered for the CY 2015 proposed rule. Each request for adding 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, we refer readers to the CMS Web site at *www.cms.gov/telehealth/*.

3. Submitted Requests and Other Additions to the List of Telehealth Services for CY 2014

We received a request in CY 2012 to add online assessment and E/M services as Medicare telehealth services effective for CY 2014. The following presents a discussion of this request, and our proposals for additions to the CY 2014 telehealth list.

a. Submitted Requests

The American Telemedicine Association (ATA) submitted a request to add CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) and 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network) to the list of Medicare telehealth services.

As we explained in the CY 2008 PFS final rule with comment period (72 FR 66371), we assigned a status indicator of ''N'' (Non-covered service) to these services because: (1) These services are non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT codes 98969 and 99444 are currently noncovered, there would be no Medicare payment if these services were furnished without the use of a telecommunications system. Since these codes are noncovered services for which no payment may be made under Medicare, we are not proposing to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2014.

b. Other Additions

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.

For CY 2013, CMS finalized a payment policy for new 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) and CPT code 99496 (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 high complexity during the service period face-to-face visit, within 7 calendar days of discharge). These services are for a patient whose medical and/or psychosocial problems require moderate or high complexity medical decision making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospitalization, observation status in a hospital, or skilled nursing facility/nursing facility, to the patient's community setting (home, domiciliary, rest home, or assisted living). Transitional care management is comprised of one face-to-face visit within the specified time frames following a discharge, in combination with non-face-to-face services that may be performed by the physician or other qualified health care professional and/or licensed clinical staff under his or her direction.

We believe that that the interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the TCM services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under category 1. Specifically, we believe that the required face-to-face visit component of TCM services is similar to the office/outpatient evaluation and management visits described by CPT codes 99201–99205 and 99211–99215. We note that like certain other non-face-to-face PFS services, the other components of the TCM service are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of the TCM service are similar to other telehealth services. Were these components of the TCM services separately billable, they would not need to be on the telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology. Therefore, we are proposing to add CPT codes 99495 and 99496 to the list of telehealth services for CY 2014 on a category 1 basis. Consistent with this proposal, we are also proposing to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include TCM services as Medicare telehealth services.

4. Telehealth Frequency Limitations

The ATA asked that we remove the telehealth frequency limitation for subsequent nursing facility services reported by CPT codes 99307 through 99310. Subsequent nursing facility services were added to the list of Medicare telehealth services in the CY 2011 PFS final rule (75 FR 73317 through 73318), with a limitation of one telehealth subsequent nursing facility care service every 30 days. In the CY 2011 PFS final rule (75 FR 73615) we noted that, as specified in our regulation at § 410.78(e)(2), the federally mandated periodic SNF visits required under § 483.40(c) could not be furnished through telehealth.

The ATA requested that the frequency limitation be removed due to ''recent federal telecommunications policy changes'' and newly available information from recent studies. Specifically, the ATA pointed to the Federal Communications Commission (FCC) pilot funding of a program to facilitate the creation of a nationwide broadband network dedicated to health care, connecting public and private non-profit health care providers in rural and urban locations, and a series of studies that demonstrated the value to patients of telehealth technology.

In considering this request, we began with the analysis contained in the CY 2011 proposed rule (75 FR 73318), when we proposed to add SNF subsequent care, to the list of Medicare telehealth services. We discussed our complementary commitments to ensuring that SNF residents, given their potential clinical acuity, continue to receive in-person visits as appropriate to manage their complex care and to make sure that Medicare pays only for medically reasonable and necessary care. To meet these commitments, we believed it was appropriate to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

We then reviewed the publicly available information regarding both the FCC pilot program and the ATA-referenced studies in light of the previously stated commitments to assess whether these developments warrant a change in 30-day frequency limitation policy. Based on our review of the FCC demonstration project and the studies referenced in the request, we found no information regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days. We did note that the FCC information reflected an aim to improve access to medical specialists in urban areas for rural health care providers, and that medical specialists in urban areas can continue to use the inpatient telehealth consultation HCPCS G-codes (specifically G0406, G0407, G0408, G0425, G0426, or G0427) when reporting medically reasonable and necessary consultations furnished to SNF residents via telehealth without any frequency limitation.

We also reviewed the studies referenced by the ATA to assess whether they provided evidence that more frequent telehealth visits would appropriately serve this particular population given the potential medical acuity and complexity of patient needs. We did not find any such evidence in the studies. Three of the studies identified by the ATA were not directly relevant to SNF subsequent care services. One of these focused on using telehealth technology to treat patients with pressure ulcers after spinal cord injuries. The second focused on the usefulness of telehealth technology for patients receiving home health care services. A third study addressed the use of interactive communication technology to facilitate the coordination of care between hospital and SNF personnel on the day of hospital discharge. The ATA also mentioned a peer-reviewed presentation delivered at its annual meeting related to SNF patient care, suggesting that the presentation demonstrated that telehealth visits are better for SNF patients than in-person visits to emergency departments or, in some cases, visits to physician offices. Although we did not have access to the full presentation it does not appear to

address subsequent nursing facility services, so we do not believe this is directly relevant to the clinical benefit of SNF subsequent care furnished via telehealth. More importantly, none of these studies addresses the concerns we have expressed about the possibility that nursing facility subsequent care visits furnished too frequently through telehealth rather than in-person could compromise care for this potentially acute and complex patient population.

We remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. We are not persuaded by the information submitted by the ATA that it would be beneficial or advisable to remove the frequency limitation we established for SNF subsequent care when furnished via telehealth. Because we want to ensure that nursing facility patients with complex medical conditions have appropriately frequent, medically reasonable and necessary encounters with their admitting practitioner, we continue to believe that it is appropriate for some subsequent nursing facility care services to be furnished through telehealth. At the same time, because of the potential acuity and complexity of SNF inpatients, we remain committed to ensuring that these patients continue to receive in-person, hands-on visits as appropriate to manage their care. Therefore, we are not proposing any changes to the limitations regarding SNF subsequent care services furnished via telehealth for CY 2014.

G. Therapy Caps

1. Outpatient Therapy Caps for CY 2014

Section 1833(g) of the Act applies annual, per beneficiary, limitations on expenses considered incurred for outpatient therapy services under Medicare Part B, commonly referred to as ''therapy caps.'' There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

Until October 1, 2012, the therapy caps applied to all outpatient therapy services except those furnished by a hospital or another entity under an arrangement with a hospital described under section 1833(a)(8)(B) of the Act. For convenience, we will refer to the exemption from the caps for services described under section 1833(a)(8)(B) of the Act as the ''outpatient hospital services exemption.'' Section 3005(b) of the MCTRJCA added section 1833(g)(6) of the Act to temporarily suspend the outpatient hospital services exemption, thereby requiring that the therapy caps apply to services described under section 1833(a)(8)(B) of the Act from October 1, 2012 to December 31, 2012 for services furnished during 2012. This broadened application of the therapy caps was extended through December 31, 2013, by section 603(a) of the ATRA. In addition, section 603(b) of the ATRA amended section 1833(g)(6) of the Act to specify that during CY 2013, for outpatient therapy services paid under section 1834(g) of the Act (those furnished by a critical access hospital (CAH)), we must count towards the therapy caps the amount that would be payable for the services under Medicare Part B if the services were paid as outpatient therapy services under section 1834(k)(1)(B) of the Act, which describes payment for outpatient therapy services furnished by hospitals and certain other entities, instead of as CAH outpatient therapy services under section 1834(g) of the Act. Payment for outpatient therapy services under section 1834(k)(1)(B) of the Act is made at 80 percent of the lesser of the actual charge for the services or the applicable fee schedule amount as defined in section 1834(k)(3) of the Act. Section 1834(k)(3) of the Act defines applicable fee schedule to mean the payment amount determined under a fee schedule established under section 1848 of the Act, which refers to the PFS, or an amount under a fee schedule for comparable services as the Secretary specifies. The PFS is required as the applicable fee schedule to be used as the payment basis under section 1834(k)(3) of the Act. Section 603(b) of the ATRA also specified that nothing in the amendments to section 1833(g)(6) of the Act ''shall be construed as changing the method of payment for outpatient therapy services under 1834(g) of the Act.''

Since CY 2011, a therapy multiple procedure payment reduction (MPPR) policy has applied to the second and subsequent ''always therapy'' services billed on the same date of service for one patient by the same practitioner or facility under the same NPI. Prior to April 1, 2013, the therapy MPPR reduced the practice expense portion of office-based services by 20 percent and reduced the practice expense portion of institutional-based services by 25 percent. As of April 1, 2013, section 633(a) of the ATRA amended sections 1848(b)(7) and 1834(k) of the Act to increase the therapy MPPR to 50 percent for all outpatient therapy services furnished in office-based and institutional settings. (For more information on the MPPR and its history, see section II.B.4 of this proposed rule.)

Sections 1833(g)(1) and (3) of the Act specify that in counting services towards the cap, ''no more than the amount specified in paragraph (2) for the year shall be considered incurred expenses.'' As noted above, section 603(b) of the ATRA amended section 1833(g)(6) of the Act to require that outpatient therapy services furnished by CAHs during CY 2013 are counted towards the therapy caps using the amount that would be paid for those services under section 1834(k)(1)(B) of the Act, which is how outpatient therapy services furnished by hospitals and certain other entities are paid. Since payment for outpatient therapy services under section 1834(k)(1)(B) of the Act is made at the PFS rate and includes any applicable therapy MPPR, the amounts for incurred expenses counted toward the caps for therapy services furnished by a CAH also reflect any applicable therapy MPPR.

We believe that this is consistent with the statutory amendments made by the ATRA. Including the therapy MPPR in calculating incurred expenses for therapy services furnished by CAHs treats CAH services consistently with services furnished in other applicable settings. Therefore, therapy services furnished by CAHs during CY 2013 count towards the therapy caps using the amount that would be payable under section 1834(k)(1)(B) of the Act, which includes an applicable MPPR. For a list of the ''always therapy'' codes subject to the therapy MPPR policy, see Addendum H of this proposed rule.

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the Medicare Economic Index (MEI). Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest $10 as specified in section 1833(g)(2)(B) of the Act. The therapy cap amounts for CY 2014 will be announced in the CY 2014 PFS final rule with comment period.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been continuously extended several times through subsequent legislation (MIEA–TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, TPTCCA, and MCTRJCA). Last amended by section 603(a) of the ATRA, the Agency's current authority to provide an

exceptions process for therapy caps expires on December 31, 2013. After expenses incurred for the beneficiary's services for the year have exceeded the therapy cap, therapy suppliers and providers use the KX modifier on claims for services to request an exception to the therapy caps. By use of the KX modifier, the therapist is attesting that the services above the therapy cap are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record.

Under section 1833(g)(5)(C) of the Act, added by the MCTRJCA and extended through 2013 by the ATRA, we are required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses exceed a threshold amount of $3,700. There are two separate thresholds of $3,700, just as there are two therapy caps, and incurred expenses are counted toward the thresholds in the same manner as the caps. Under the statute, the required application of the manual medical review process expires December 31, 2013. For information on the manual medical review process, go to *www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html*.

2. Proposed Application of Therapy Caps to Services Furnished by CAHs

Section 4541 of the BBA amended section 1833(g) of the Act to create the therapy caps discussed above. This BBA provision applied the therapy caps to outpatient therapy services described at section 1861(p) of the Act except for the outpatient therapy services described in section 1833(a)(8)(B) of the Act. Section 1833(a)(8)(B) of the Act refers to therapy services furnished by a hospital to an outpatient, to services furnished to a hospital inpatient who has exhausted, or is not entitled to, benefits under Part A; and to these same services when furnished by an entity under arrangements with a hospital. Payment for the services described under section 1833(a)(8)(B) of the Act is made under section 1834(k)(1)(B) of the Act.

Section 4201 of the BBA amended section 1820 of the Act to require a process for establishment of CAHs. Payment for CAH outpatient services is described under section 1834(g) of the Act.

When we proposed language to implement the BBA provision establishing therapy caps in the CY 1999 PFS proposed rule, we indicated in the preamble that the therapy caps do not apply to therapy services furnished directly or under arrangements by a hospital or CAH to an outpatient or to an inpatient who is not in a covered Part A stay (63 FR 30818, 30858). We included a similar statement in the preamble to the final rule; however, we did not include the same reference to CAHs in that sentence in the CY 1999 PFS final rule with comment period (63 FR 58814, 58865). In the CY 1999 PFS final rule with comment period, we also stated generally that the therapy caps apply only to items and services furnished by nonhospital providers and therapists (63 FR 58865). In the CY 1999 proposed rule, we proposed to include provisions at § 410.59(e)(3) and § 410.60(e)(3) to describe, respectively, the outpatient therapy services that are exempt from the statutory therapy caps for outpatient OT services, and for outpatient PT and SLP services combined. Specifically, in the CY 1999 PFS proposed rule, we proposed to add the following regulatory language for OT and for PT at §§ 410.59(e)(3) and 410.60(e)(3): ''For purposes of applying the limitation, outpatient [occupational therapy/physical therapy] excludes services furnished by a hospital or CAH directly or under arrangements'' (63 FR 30880). However, in the CY 1999 PFS final rule with comment period, the phrase ''or CAH'' was omitted from the final regulation text for OT in § 410.59(e)(3), but was included in the final regulation text for PT in § 410.60(e)(3). We note that for purposes of the therapy cap, outpatient PT services under our regulation at § 410.60 include outpatient SLP services described under § 410.62. As such, SLP services are included in the references to PT under § 410.60. Although the rulemaking history and regulations appear inconclusive as to whether outpatient therapy services furnished by CAHs were intended to be subject to the therapy caps between January 1, 1999 and October 1, 2012, we believe that we inadvertently omitted the phrase ''or CAH'' in the CY 1999 final regulation for the occupational therapy cap. Moreover, we have consistently excluded all outpatient therapy services furnished by CAHs from the therapy caps over this time frame, whether the services were PT, SLP, or OT.

Accordingly, from the outset of the therapy caps under section 1833(g) of the Act, therapy services furnished by CAHs have not been subject to the therapy caps. Thus, CAHs have not been required to use the exceptions process (including the KX modifier and other requirements) when furnishing medically necessary therapy services above the therapy caps; and therapy services furnished by CAHs above the threshold amounts have not been subject to the manual medical review process. Similarly, until section 603(b) of the ATRA amended the statute to specify the amount that must be counted towards the therapy caps and thresholds for outpatient therapy services furnished by CAHs, we did not apply towards the therapy caps or thresholds any amounts for therapy services furnished by CAHs. Therefore, we have interpreted the statutory exclusion for outpatient therapy services furnished by hospital outpatient departments also to apply to CAHs and implemented the therapy caps accordingly.

As noted above, section 3005(b) of the MCTRJCA temporarily suspended the outpatient hospital services exemption from October 1, 2012 through December 31, 2012 (which has subsequently been extended by the ATRA through December 31, 2013). As a result, from October 1, 2012 to the present, CAH services have been treated differently than services furnished in other outpatient hospital settings. In implementing this change required by the MCTRJCA, we had reason to assess whether, as a result of the amendment, the therapy caps should be applied to outpatient therapy services furnished by CAHs. We concluded that the MCTRJCA amendment did not make the therapy caps applicable to services furnished by CAHs for which payment is made under section 1834(g) of the Act because it affected only the outpatient hospital services described under section 1833(a)(8)(B) of the Act for which payment is made under section 1834(k)(1)(B) of the Act. With the enactment in section 603(b) of the ATRA of specific language requiring us to count amounts toward the therapy caps and thresholds for services furnished by CAHs, we again had reason to assess whether the therapy caps apply to services furnished by CAHs. We concluded that the ATRA amendment did not explicitly make the therapy caps applicable to services furnished by CAHs, but directed us to count CAH services towards the caps. However, after reflecting on the language of section 1833(g) of the Act, we have concluded that the therapy caps should be applied to outpatient therapy services furnished by CAHs.

To explain further, under sections 1833(g)(1) and (3) of the Act, the therapy caps are made applicable to all services described under section 1861(p) of the Act except those described under the outpatient hospital services exemption. Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services, (expressly for PT

services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services). Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Under section 1861(u) of the Act, a CAH is a ''provider of services.'' As such, unless the outpatient therapy services furnished by a CAH fit within the outpatient hospital services exemption under section 1833(a)(8)(B) of the Act, the therapy caps would be applicable to PT, SLP, OT services furnished by a CAH. As noted above, section 1833(a)(8)(B) of the Act describes only outpatient therapy services for which payment is made under section 1834(k) of the Act. Payment for CAH services is made under section 1834(g) of the Act. Thus, the outpatient hospital services exemption to the therapy caps under section 1833(a)(8)(B) of the Act does not apply, and the therapy caps are applicable, to outpatient therapy services furnished by a CAH.

However, we recognize that our current regulation specifically excludes PT and SLP services furnished by CAHs from the therapy caps, and our consistent practice since 1999 has been to exclude PT, SLP and OT services furnished by CAHs from the therapy caps. As such, in order to apply the therapy caps and related policies to services furnished by CAHs for CY 2014 and subsequent years, we believe we would need to revise our regulations.

We propose to apply the therapy cap limitations and related policies to outpatient therapy services furnished by a CAH beginning on January 1, 2014. Not only do we believe this is the proper statutory interpretation, but we also believe it is the appropriate policy. Under the existing regulations, with the suspension of the outpatient hospital services exemption through 2013, the therapy caps apply to outpatient therapy services paid under Medicare Part B and furnished in all applicable settings except CAHs. We believe that outpatient therapy services furnished by a CAH should be treated consistently with outpatient therapy services furnished in all other settings. Therefore, we propose to revise the therapy cap regulation at § 410.60(e)(3) to remove the exemption for services furnished by a CAH.

CAH outpatient therapy services are distinct from other outpatient therapy services in that outpatient therapy services furnished in office-based or other institutional settings are paid at the rates contained in the PFS, whereas CAHs are paid for outpatient therapy services under the methodology described under section 1834(g) of the Act. Because the CAH reasonable cost-based payment amounts are reconciled at cost reporting year-end, and are different from the fee schedule-based payments for other outpatient therapy services, it might have been difficult to identify the amounts that we should have accrued towards the therapy caps for services furnished by CAHs. Therefore, prior to 2013, not only did CMS not apply any caps to services provided by a CAH, but also did not count CAH services towards the caps. However, the ATRA amended the statute to require for outpatient therapy services furnished by CAHs during 2013 that we count towards the caps and the manual medical review thresholds the amount that would be payable for the services under Medicare Part B as if the services were paid as outpatient therapy services under section 1834(k)(1)(B) of the Act instead of as CAH services under section 1834(g) of the Act. Thus, the distinction in payment methodology no longer provides a technical barrier to including an amount for therapy services furnished by CAHs in the caps. We propose to continue this methodology of counting the amount payable under section 1834(k)(1)(B) of the Act towards the therapy cap and threshold for services furnished by CAHs in CY 2014 and subsequent years.

We recognize that the outpatient hospital services exemption is suspended under current law only through December 31, 2013. If this provision is not extended, with our proposal to apply the therapy caps to services furnished by CAHs, effective January 1, 2014, therapy services furnished by CAHs would be treated differently than services furnished in other outpatient hospital settings. We note that the exceptions process described above, including use of the KX modifier to attest to the medical necessity of therapy services above the caps and other requirements, would apply for services furnished by a CAH in the same way that it applies to outpatient therapy services furnished by certain other facilities. Similarly, the manual medical review process for claims that exceed the $3,700 thresholds would apply to therapy services furnished by a CAH in the same way that they apply for outpatient therapy services furnished by certain other facilities. We recognize that the manual medical review process expires on December 31, 2013 and we would apply the manual medical review process to CAH services only as required by statute. We are proposing to amend the regulations establishing the conditions for PT, OT, and SLP services by removing the exemption of CAH services from the therapy caps and specifying that the therapy caps apply to such services.

Specifically, we propose to amend the regulations, which pertain to the OT therapy cap and the combined PT and SLP therapy cap, respectively, by including paragraph (e)(1)(iv) under § 410.59 and (e)(1)(iv) under § 410.60 to specify that (occupational/physical) therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(B) of the Act. We also propose to add new paragraph (e)(2)(v) to § 410.59 and (e)(2)(vi) to § 410.60. These new paragraphs would expressly include outpatient (occupational/physical) therapy services furnished by a CAH directly or under arrangements under the description of services to which the annual limitation applies. Further, we propose to amend the regulation at § 410.60(e)(3), which currently excludes services furnished by a CAH from the therapy cap for PT and SLP services, to remove the phrase ''or CAH.''

H. Requirements for Billing ''Incident To'' Services

Section 1861(s)(2)(A) of the Act establishes the benefit category for services and supplies furnished as ''incident to'' the professional services of a physician. The statute specifies that ''incident to'' services and supplies are ''of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in physicians' bills.''

In addition to the requirements of the statute, our regulation at § 410.26 sets forth specific requirements that must be met in order for physicians and other practitioners to bill Medicare for incident to physicians' services. Section 410.26(a)(7) limits ''incident to'' services to those included under section 1861(s)(2)(A) of the Act and that are not covered under another benefit category. Section 410.26(b) specifies (in part) that

in order for services and supplies to be paid as ''incident to'' services under Medicare Part B, the services or supplies must be:

- Furnished in a noninstitutional setting to noninstitutional patients.
- An integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
- Furnished under direct supervision (as specified under § 410.26(a)(2) and defined in § 410.32(b)(3)(ii)) of a physician or other practitioner eligible to bill and directly receive Medicare payment.
- Furnished by the physician, practitioner with an ''incident to'' benefit, or auxiliary personnel.

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

''Incident to'' services are treated as if they were furnished by the billing practitioner for purposes of Medicare billing and payment. Consistent with this terminology, in this discussion when referring to the practitioner furnishing the service, we mean the practitioner who is billing for the service. When we refer to the ''auxiliary personnel'' or the person who ''provides'' the service we are referring to an individual who is personally performing the service or some aspect of it. Since we treat ''incident to'' services as services furnished by the billing practitioner for purposes of Medicare billing and payment, payment is made to the billing practitioner under the PFS, and all relevant Medicare rules apply including, but not limited to, requirements regarding medical necessity, documentation, and billing. Those practitioners who can bill Medicare for ''incident to'' services are paid at their applicable Medicare payment rate as if they furnished the service. For example, when ''incident to'' services are billed by a physician, they are paid at 100 percent of the fee schedule amount, and when the services are billed by a nurse practitioner or clinical nurse specialist, they are paid at 85 percent of the fee schedule amount. Payments are subject to the usual deductible and coinsurance.

As the services commonly furnished in physicians' offices and other nonfacility settings have expanded to include more complicated services, the types of services that can be furnished ''incident to'' physicians' services have also expanded. States have increasingly adopted standards regarding the delivery of health care services in all settings, including physicians' offices, in order to protect the health and safety of their citizens. These state standards often include qualifications for the individuals who are permitted to furnish specific services or requirements about the circumstances under which services may be actually furnished. For example, since 2009, New York has required that offices in which surgery is furnished must be accredited by a state-approved accredited agency or organization. Similarly, Florida requires certain standards be met when surgery is furnished in offices, including that the surgeon must ''examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed'' and ''qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.''

Over the past years, several situations have come to our attention where Medicare was billed for ''incident to'' services that were provided by auxiliary personnel who did not meet the state standards for those services in the state in which the services were furnished. The physician or practitioner billing for the services would have been permitted under state law to personally furnish the services, but the services were actually provided by auxiliary personnel who were not in compliance with state law in providing the particular service (or aspect of the service).

Practitioners authorized to bill Medicare for services that they furnish to Medicare beneficiaries are required under Medicare to comply with state law. For example, section 1861(r) of the Act specifies that an individual can be considered a physician in the performance of any function or action only when legally authorized to practice in the particular field by the State in which he performs such function or action. Section 410.20(b) of our regulations provides that payment is made for services only if furnished by a doctor who is ''. . . legally authorized to practice by the state in which he or she performs the functions or actions, and who is acting within the scope of his or her license.'' Similarly, section 1861(s)(2)(K)(ii) of the Act provides a benefit category for services of a nurse practitioner (NP) or clinical nurse specialist (CNS) that the NP or CNS is ''legally authorized to perform by the State in which the services are performed, and § 410.75(b) of our regulations provides that nurse practitioners' services are covered only if the NP is ''authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law.'' There are similar provisions for clinical psychologist services (§ 410.71(a)(2)), clinical social worker services (§ 410.73(b)(1)), physician assistants' services (§ 410.74(a)(2)(ii)), clinical nurse specialists' services (§ 410.76(b)(1)), and certified nurse-midwives' services (§ 410.77(b)(1)).

However, the Medicare requirements for services and supplies incident to a physician's professional services (§ 410.26 discussed above), do not specifically make compliance with state law a condition of payment for services (or aspects of services) and supplies furnished and billed as ''incident to'' services. Nor do any of the regulations regarding services furnished ''incident to'' the services of other practitioners contain this requirement. Thus, Medicare has had limited recourse when services furnished incident to a physician's or practitioner's services are not furnished in compliance with state law.

In 2009, the Office of Inspector General issued a report entitled ''Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services'' (OEI–09–06–00430) that considered in part the qualifications of auxiliary personnel providing incident to physician services. This report found that services were being billed to Medicare that were provided by auxiliary personnel. After finding that services were being provided and billed to Medicare by auxiliary personnel ''. . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rules,'' the OIG recommended that we revise the ''incident to'' rules to, among other things, ''require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except . . . nonphysicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician.'' We are also proposing amendments to our regulations to address this recommendation.

To ensure that auxiliary personnel providing services to Medicare

beneficiaries incident to the services of other practitioners do so in accordance with the requirements of the state in which the services are furnished and to ensure that Medicare dollars can be recovered when such services are not furnished in compliance with the state law, we are proposing to add a requirement to the ''incident to'' regulations at § 410.26, Services and supplies incident to a physician's professional services: Conditions. Specifically, we are proposing to amend § 410.26(b) by redesignating paragraphs (b)(7) and (b)(8) as paragraphs (b)(8) and (b)(9), respectively, and by adding a new paragraph (b)(7) to state that ''Services and supplies must be furnished in accordance with applicable State law.'' We are also proposing to amend the definition of auxiliary personnel at § 410.26(a)(1) to require that the individual performing ''incident to'' services ''meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.''

In addition, we are proposing to eliminate redundant and potentially incongruent regulatory language by replacing the specific ''incident to'' requirements currently contained in the regulations relating to each of the various types of practitioners with a reference to the requirements of § 410.26. Specifically, we are proposing to:

- Revise § 410.71(a)(2) regarding clinical psychologist services to read ''Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of § 410.26 are met.''
- Revise § 410.74(b) regarding physician assistants' services to read ''Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of § 410.26 are met.''
- Revise § 410.75(d) regarding nurse practitioners to read ''Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.''
- Revise § 410.76(d) regarding clinical nurse specialists' services to read with ''Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of § 410.26 are met.''
- Revise the language in § 410.77(c) regarding certified nurse-midwives' services to read ''Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.''

As discussed above, these practitioners are, and would continue to be under this proposal, required to comply with § 410.26 for services furnished incident to their professional services. We believe it is redundant and potentially confusing to have separate regulations that generally restate the requirements for ''incident to'' services of § 410.26 using slightly different terminology. Our goal in proposing the revisions to refer to § 410.26 in the regulation for each practitioner's ''incident to'' services is to reduce the regulatory burden and make it less difficult for practitioners to determine what is required. Reconciling these regulatory requirements for physicians and all other practitioners who have the authority to bill Medicare for ''incident to'' services is also consistent with our general policy to treat nonphysician practitioners similarly to physicians unless there is a compelling reason for disparate treatment. We believe that this proposal would make the requirements clearer for practitioners furnishing ''incident to'' services without eliminating existing regulatory requirements or imposing new ones. We welcome comments on any requirements that we may have inadvertently overlooked in our proposed revisions, or any benefit that accrues from continuing to carry these separate regulatory requirements.

The regulations applicable to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) have similar ''incident to'' rules, and we are proposing to make conforming changes to these regulations. Specifically, we are also proposing to revise § 405.2413(a), which addresses services and supplies incident to physicians' services for RHCs and FQHCs, by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that states services and supplies must be furnished in accordance with applicable state law. Additionally, we are proposing to amend § 405.2415(a), which addresses services incident to nurse practitioner and physician assistant services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that specifies services and supplies must be furnished in accordance with applicable state law. We are proposing to amend § 405.2452(a), which addresses services and supplies incident to clinical psychologist and clinical social worker services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that states services and supplies must be furnished in accordance with applicable state law. Finally, we are also proposing the removal of the word ''personal'' in §§ 405.2413, 405.2415, and 405.2452 to be consistent with the ''incident to'' provisions in § 410.26 Services and supplies incident to a physician's professional services: Conditions.

The proposed amendments to our regulations are consistent with the traditional approach of relying primarily on the states to regulate the health and safety of their residents in the delivery of health care services. Throughout the Medicare program, as evidenced by several examples above, the qualifications required for the delivery of health care services are generally determined with reference to state law. As discussed above, our current regulations governing practitioners who can bill Medicare directly include a basic requirement to comply with state law when furnishing Medicare covered services. However, the Medicare regulations for ''incident to'' services and supplies do not specifically make compliance with state law a condition of payment for services and supplies furnished and billed as an incident to a practitioner's services. The proposed amendments to our regulations would rectify this situation and make compliance with state law a requirement for all ''incident to'' services. In addition to health and safety benefits we believe would accrue to the Medicare patient population, this approach would assure that federal dollars are not expended for services that do not meet the standards of the states in which they are being furnished, and provides the ability for the federal government to recover funds paid where services and supplies are not furnished in accordance with state law.

We note that this proposal would not impose any new requirements on those practitioners billing the Medicare program since auxiliary personnel furnishing services in a state would already be required to comply with the laws of that state. This regulatory change would simply adopt the existing requirements as a condition of payment under Medicare. Codifying this requirement would provide the federal government a clear basis to deny a claim for Medicare payment when services are not furnished in accordance with applicable state law and the ability to recover funds, as well as assure that Medicare makes payment for services furnished to beneficiaries only when the services meet the requirements imposed by the states to regulate health care delivery in order to ensure the health and safety of their citizens.

I. Complex Chronic Care Management Services

As we discussed in the CY 2013 PFS final rule with comment period, we are committed to 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 *innovations.cms.gov/initiatives/ACO/Pioneer/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 *innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html*).
- 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 *www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf* and the Innovation Center's Web site at *innovations.cms.gov/initiatives/FQHCs/index.html*).
- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's Web site at *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 coordination with these initiatives, we also continue 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). We view potential refinements to the PFS such as these as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

1. Patient Eligibility for Separately Payable Non-Face-to-Face Complex Chronic Care Management Services

Under current PFS policy, the payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits because care management is a component of those E/M services. The pre- and post-encounter non-face-to-face care management work is included in calculating the total work for the typical E/M services, and the total work for the typical service is used to develop RVUs for the E/M services. In the CY 2012 PFS proposed rule, we highlighted some of the E/M services that include substantial care management work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include furnishing care management, communication, and other necessary care management related to the office visit in the post-service work (76 FR 42917).

However, the physician community continues to tell us that the care management included in many of the E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work involved for certain categories of beneficiaries. Because the current E/M office/outpatient visit CPT codes were designed to support all office visits and reflect an overall orientation toward episodic treatment, we agree that these E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. For example, we currently pay physicians separately for the non face-to-face care plan oversight services furnished to beneficiaries under the care of home health agencies or hospices and we currently pay separately for care management services furnished to beneficiaries transitioning from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community.

Similar to these situations, we believe that the resources required to furnish complex chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions are not adequately reflected in the existing E/M codes. Furnishing care management to beneficiaries with multiple chronic conditions requires complex and multidisciplinary care modalities that involve: Regular physician development and/or revision of care plans; subsequent reports of patient status; review of laboratory and other studies; communication with other health professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustment of medical therapy. Therefore, for CY 2015, we are proposing to establish a separate payment under the PFS for complex chronic care management services furnished to patients with multiple complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

We have performed an analysis of Medicare claims for patients with selected multiple chronic conditions (see *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf*). This analysis indicated that patients with these selected multiple chronic conditions are at increased risk for hospitalizations, use of post-acute care services, and emergency department visits. We believe these findings would hold in general for patients with multiple

complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We believe that successful efforts to improve chronic care management for these patients could improve the quality of care while simultaneously decreasing costs (for example, through reductions in hospitalizations, use of post-acute care services, and emergency department visits.)

As described below in more detail in section II.I.3, we intend to develop standards for furnishing complex chronic care management services to ensure that the physicians who bill for these services have the capability to provide them. One of the primary reasons for our proposed 2015 implementation date is to provide sufficient time to develop and obtain public input on the standards necessary to demonstrate the capability to provide these services.

2. Scope of Complex Chronic Care Management Services

We consider the scope of complex chronic care management services to include:

- The provision of 24-hour-a-day, 7-day-a-week access to address a patient's acute complex chronic care needs. To accomplish these tasks, we would expect that the patient would be provided with a means to make timely contact with health care providers in the practice to address urgent complex chronic care needs regardless of the time of day or day of the week. Members of the complex chronic care team who are involved in the after-hours care of a patient must have access to the patient's full electronic medical record even when the office is closed so they can continue to participate in care decisions with the patient.
- 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. In consultation with the patient and other key practitioners treating the patient, the practitioner furnishing complex chronic care management services should create a patient-centered plan of care 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. It typically includes, but is not limited to, the following elements: Problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan. The provider should seek to reflect a full list of problems, medications and medication allergies in the electronic health record to inform the care plan, care coordination and ongoing clinical care.
- Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. The practice must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way so as to reduce the need for repeat visits to emergency departments and re-admissions to hospitals and skilled nursing facilities.
- Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in practice's medical record system.
- Enhanced opportunities for a patient to communicate with the provider regarding their care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

3. Standards for Furnishing Complex Chronic Care Coordination Services

Not all physicians and qualified nonphysician practitioners who wish to furnish complex chronic care management services currently have the capability to fully provide the scope of services described in section II.I.2. without making additional investments in technology, staff training, and the development and maintenance of systems and processes to furnish the services. We intend to establish standards that would be necessary to provide high quality, safe complex chronic care management services. For example, potential standards could include the following:

- The practice must be using a certified Electronic Health Record (EHR) for beneficiary care that meets the most recent HHS regulatory standard for meaningful use. The EHR must be integrated into the practice to support access to care, care coordination, care management and communication.
- The practice must employ one or more advanced practice registered nurses or physicians assistants whose written job descriptions indicate that their job roles include and are appropriately scaled to meet the needs for beneficiaries receiving services in the practice who require complex chronic care management services provided by the practice.
- The practice must be able to demonstrate the use of written protocols by staff participating in the furnishing of services that describe: (1) The methods and expected ''norms'' for furnishing each component of complex chronic care management services provided by the practice; (2) the strategies for systematically furnishing health risk assessments to identify all beneficiaries eligible and who may be willing to participate in the complex chronic care management services; (3) the procedures for informing eligible beneficiaries about complex chronic care management services and obtaining their consent; (4) the steps for monitoring the medical, functional and social needs of all beneficiaries receiving complex chronic care management services; (5) system based approaches to ensure timely delivery of all recommended preventive care services to beneficiaries; (6) guidelines for communicating common and anticipated clinical and non-clinical issues to beneficiaries; (7) care plans for beneficiaries post-discharge from an emergency department or other institutional health care setting, to assist beneficiaries with follow up visits with clinical and other suppliers or providers, and in managing any changes in their medications; (8) a systematic approach to communicate and electronically exchange clinical information with and coordinate care among all service providers involved in

the ongoing care of a beneficiary receiving complex chronic care management services; (9) a systematic approach for linking the practice and a beneficiary receiving complex chronic care management services with long-term services and supports including home and community-based services; (10) a systematic approach to the care management of vulnerable beneficiary populations such as racial and ethnic minorities and people with disabilities; and (11) patient education to assist the beneficiary to self-manage a chronic condition that is considered at least one of his/her complex chronic conditions. These protocols must be reviewed and updated as is appropriate based on the best available clinical information at least annually.

• All practitioners including advanced practice registered nurses or physicians assistants, involved in the delivery of complex chronic care management services must have access at the time of service to the beneficiary's EHR that includes all of the elements necessary to meet the most recent HHS regulatory standard for meaningful use. This includes any and all clinical staff providing after hours care to ensure that the complex chronic care management services are available with this level of EHR support in the practice or remotely through a Virtual Private Network (VPN), a secure Web site, or a health information exchange (HIE) 24 hours per day and 7 days a week.

Some have suggested that, to furnish these services, practices could be recognized as a medical home by one of the national organizations including: the National Committee for Quality Assurance (NCQA), the Accreditation Association for Ambulatory Health Care, The Joint Commission, URAC, etc.; which are formally recognizing primary care practices as a patient-centered medical home. We understand there are differences among the approaches taken by national organizations that formally recognize medical homes and therefore, we seek comment on these and other potential care coordination standards, and the potential for CMS recognizing a formal patient-centered medical home designation as one means for a practice to demonstrate it has met any final care coordination standards for furnishing complex chronic care management services. Any regulatory changes would be addressed through separate notice-and-comment rulemaking.

4. Billing for Separately Payable Complex Chronic Care Management Services and Obtaining Informed Consent From the Beneficiary

To recognize the additional resources required to provide complex chronic care management services to patients with multiple chronic conditions, we are proposing to create two new separately payable alphanumeric G-codes.

Complex chronic care management services furnished to patients with multiple (two or more) complex 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;

GXXX1, initial services; one or more hours; initial 90 days

GXXX2, subsequent services; one or more hours; subsequent 90 days

Typically, we would expect the one or more hours of services to be provided by clinical staff directed by a physician or other qualified health care professional. Initial services include obtaining the initial informed consent from the beneficiary as described below and the initial implementation of the complex chronic care management services described in section II.I.2. of this proposed rule.

Not all patients who are eligible for separately payable complex chronic care management services may necessarily want these services to be provided. Therefore, before the practitioner can furnish or bill for these services, the eligible beneficiary must be informed about the availability of the services from the practitioner and provide his or her consent to have the services provided, including the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient about what complex chronic care management services are, how these services are accessed, how their information will be shared among other providers in the care team, and that cost-sharing applies to these services even when they are not delivered face-to-face in the practice. To bill for the initial services (GXXX1), the practitioner would be required to document in the patient's medical record that all of the complex chronic care management services were explained and offered to the patient, noting the patient's decision to accept these services. Also, a written or electronic copy of the care plan would be provided to the beneficiary and this would also be recorded in the beneficiary's electronic medical record.

A practitioner would need to reaffirm with the beneficiary at least every 12 months whether he or she wishes to continue to receive complex chronic care management services during the following 12-month period.

The informed consent for complex chronic care management services could be revoked by the beneficiary at any time. However, if the revocation occurs during a current 90-day complex chronic care management period, the revocation would not be effective until the end of that period. The beneficiary could notify the practitioner either verbally or in writing. At the time the informed consent is obtained, the practitioner would be required to inform the beneficiary of the right to stop the complex chronic care management services at any time and the effect of a revocation of consent on complex chronic care management services. Revocation by the beneficiary of the informed consent must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the practitioner would not be providing complex chronic care management services beyond the current 90 day period.

A beneficiary who has revoked informed consent for complex chronic care management services from one practitioner may choose instead to receive these services from a different practitioner, which can begin at the conclusion of the current 90-day period. The new practitioner would need to fulfill all the requirements for billing GXXX1 and then GXXX2.

Prior to submitting a claim for complex chronic care management services, the practitioner must notify the beneficiary that a claim for these services will be submitted to Medicare. The notification must indicate: that the beneficiary has been receiving these services over the previous 90-day period (noting the beginning and end dates for the 90-day period), the reason(s) why the services were provided and a description of the services provided. The notice may be delivered by a means of communication mutually agreed to by the practitioner and beneficiary such as mail, email, or facsimile, or in person (for example, at the time of an office visit.) The notice must be received by the beneficiary before the practitioner submits the claim for the services. A separate notice must be received by the beneficiary for each 90-day period for which the services will be billed. A copy of the notice should be included in the medical record.

In addition to the requirement that at least an hour of complex chronic care

management services be furnished to the patient, we propose that billing for subsequent complex chronic care management services (GXXX2) would be limited to those 90-day periods in which the medical needs of the patient require substantial revision of the care plan discussed in section II.I.2. Substantial revision to a care plan typically is required when the patient's clinical condition changes sufficiently to require: Significantly more intensive monitoring by clinical staff, significant changes in the treatment regimen, and significant time to educate the patient/caregiver about the patient's condition/change in treatment plan and prognosis.

Because the payment for non-face-to-face care management services is generally bundled into the payment for face-to-face E/M visits, the resources required to provide care management services for patients without multiple chronic conditions or for less than the one or more hours of clinical staff time continues to be reflected in the payment for face-to-face E/M visits. For similar reasons, the resources required to provide care management services to patients residing in facility settings where care management activity by facility staff would be included in the associated facility payment also continues to be reflected in the payment for face-to-face E/M visits.

We propose that complex chronic care management services include transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), and hospice care supervision (HCPCS G0182). If furnished, in order to avoid duplicate payment, we propose that these services may not be billed separately during the 90 days for which either GXXX1 or GXXX2 are billed. For similar reasons, we propose that GXXX1 or GXXX2 cannot be billed separately if ESRD services (CPT 90951–90970) are billed during the same 90 days.

Practitioners billing a complex chronic care management code accept responsibility for managing and coordinating the beneficiary's care over this period. Therefore, we propose to pay only one claim for the complex chronic care management services (either GXXX1 or GXXX2) billed per beneficiary at the conclusion of each 90-day period. All of the complex chronic care management services delineated in section II.H.2 above that are relevant to the patient must be furnished in order to bill GXXX1 or GXXX2 for a 90-day period.

If a face-to-face visit is provided during the 90-day period by the practitioner who is furnishing complex chronic care management services, the practitioner should report the appropriate evaluation and management code in addition to GXXX1 or GXXX2.

We note that to bill for these services, we propose that at least 60 minutes of complex chronic care management services must be provided. Time of less than 60 minutes over the 90 day period could not be rounded up to 60 minutes in order to bill for these services. We also propose that for purposes of meeting the 60-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

In future rulemaking, we intend to propose RVUs for complex chronic care management services. To inform our proposal, we seek input on the physician work and practice expenses associated with these services.

5. Complex Chronic Care Management Services and the Annual Wellness Visit (AWV) (HCPCS codes G0438, G0439)

We are proposing that a beneficiary must have received an AWV in the past twelve months in order for a practitioner to be able to bill separately for complex chronic care management services. We believe that the linking of these services to the AWV makes sense for several reasons. First, the AWV is designed to enable a practitioner to systematically capture information that is essential for the development of a care plan. This includes the establishment of a list of current practitioners and suppliers that are regularly involved in providing medical care to the beneficiary, the assessment of the beneficiary's functional status related to chronic health conditions, the assessment of whether the beneficiary suffers from any cognitive limitations or mental health conditions that could impair self-management of chronic health conditions, and an assessment of the beneficiary's preventive health care needs including those that contribute to or result from a beneficiary's chronic conditions. Second, the beneficiary's selection of a practitioner to furnish the AWV is a useful additional indicator to assist us in knowing which single practitioner a beneficiary has chosen to furnish complex chronic care management services. While a beneficiary would retain the right to choose and change the practitioner to furnish complex chronic care management services, we do not believe that it is in the interest of a beneficiary to have more than one practitioner at a time coordinating the beneficiary's care and we do not intend to pay multiple practitioners for furnishing these services over the same time period. Third, the AWV is updated annually which is consistent with the minimal interval for reviewing and modifying the care plan required for the complex chronic care management services.

We would expect that the practitioner the beneficiary chooses for the AWV would be the practitioner furnishing the complex chronic care management services. For the less frequent situations when a beneficiary chooses a different practitioner to furnish the complex chronic care management services from the practitioner who in the previous year furnished the AWV, the practitioner furnishing the complex chronic are management services would need to obtain a copy of the assessment and care plan developed between the beneficiary and the practitioner who furnished the AWV prior to billing for complex chronic care management services.

Because a beneficiary is precluded from receiving an AWV within 12 months after the effective date of his or her first Medicare Part B coverage period, for that time period we propose the Initial Preventive Physical Examination (G0402) can substitute for the AWV to allow a beneficiary to receive complex chronic care management services.

6. Complex Chronic Care Management Services Furnished Incident to a Physician's Service Under General Physician Supervision

We outline the requirements for billing for services furnished in the office, but not personally and directly performed by the physician or qualified nonphysician practitioner (referred to as a ''practitioner'' in the following discussion), under our ''incident to'' requirements in regulations and in section 60, Chapter 12, of Medicare Benefit Policy Manual (100–02). One key requirement of ''incident to'' services is that a practitioner (as the term is used in section II.H of this proposed rule directly supervise the provision of services by auxiliary personnel by being in the office suite and able to furnish assistance and direction throughout the provision of the service. Section 60.4 of the Manual specifically discusses the one exception that allows for general supervision of ''incident to'' services furnished to homebound patients in medically underserved areas. Under that provision, we identify more specific requirements for the personnel that can furnish ''incident to'' services under general supervision. For example, we require that the personnel must be

employed by, employed by the same entity, or an independent contractor of, the practitioner billing the ''incident to'' services.

One of the required capabilities for a physician to furnish complex chronic care management services is 24-hour-a-day, 7-day-a-week beneficiary access to the practice to address the patient's complex chronic care needs. We would expect that the patient would be provided with a means to make timely contact with health care providers in the practice to address those needs regardless of the time of day or day of the week. If the patient has a complex chronic care need outside of the practice's normal business hours, the patient's initial contact with the practice for that need could be with clinical staff employed by the practice, (for example, a nurse or other appropriate auxiliary personnel) and not necessarily with a physician or practitioner. Those services would be furnished incident to the services of the billing practitioner.

We have also proposed to require that at least one hour of complex chronic care services be furnished to a patient during the 90-day period in order for the practitioner to be able to bill separately for the chronic care services. The time, if not personally performed by the physician, must be directed by the physician. We are proposing that the time spent by a clinical staff person furnishing aspects of complex chronic care services outside of the practice's normal business hours during which there is no direct physician supervision would count towards the one hour requirement even though the services do not meet the direct supervision requirement for ''incident to'' services.

We believe that the additional requirements we impose for personnel under the exception for general supervision for homebound patients in medically underserved areas should apply in these circumstances where we are allowing a practitioner to bill Medicare for complex chronic care management services furnished under their general supervision and incident to their professional services. In both of these unusual cases, these requirements help to ensure that appropriate services are being furnished by appropriate personnel in the absence of the direct supervision. Specifically, we propose that if a practice meets all the conditions required to bill separately for complex chronic care management services, the time spent by a clinical staff employee furnishing aspects of these services to address a patient's complex chronic care need outside of the practice's normal business hours is counted towards the one hour requirement when at a minimum the following conditions are met:

- The clinical staff person is directly employed by the physician and the employed clinical staff person meets any relevant state requirements.
- The services of the clinical staff person are an integral part of the physician's complex chronic care management services to the patient (the patient must be one the physician is treating and for which informed consent is in effect), and are performed under the general supervision of the physician. General supervision means that the physician need not be physically present when the services are performed; however, the services must be performed under the physician's overall supervision and control. Contact is maintained between the clinical staff person and the physician (for example, the employed clinical staff person contacts the physician directly if warranted and the physician retains professional responsibility for the service.)
- The services of the employed clinical staff person meet all other ''incident to'' requirements with the exception of direct supervision.

7. Complex Chronic Care Management Services and the Primary Care Incentive Payment Program (PCIP)

Under section 1833(x) of the Act, the PCIP provides a 10 percent incentive payment for primary care services within a specific range of E/M services when furnished by a primary care practitioner. Specific physician specialties and qualified nonphysician practitioners can qualify as primary care practitioners if 60 percent of their PFS allowed charges are primary care services. As we explained in the CY 2011 PFS final rule (75 FR 73435 through 73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, to avoid inadvertently disqualifying community primary care physicians who follow their patients into the hospital setting, we finalized a policy to remove allowed charges for certain E/M services furnished to hospital inpatients and outpatients from the total allowed charges in the PCIP primary care percentage calculation. In the CY 2013 final rule (77 FR 68993), we adopted a policy that the TCM code should be treated in the same manner as those services for the purposes of PCIP because post-discharge TCM services are a complement in the community setting to the hospital-based discharge day management services already excluded from the PCIP denominator. Similar to the codes already excluded from the PCIP denominator, we expressed concern that inclusion of the TCM code in the denominator of the primary care percentage calculation could produce unwarranted bias against ''true primary care practitioners'' who are involved in furnishing post-discharge care to their patients.

Complex chronic care management services are also similar to the services that we have already excluded from the from the PCIP denominator. For example, complex chronic care management includes management of care transitions within health care settings including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. Therefore, while physicians and qualified nonphysician practitioners who furnish complex chronic care management services would not receive an additional incentive payment under the PCIP for the service itself (because it is not considered a ''primary care service'' for purposes of the PCIP), we propose that the allowed charges for complex chronic care management services would not be included in the denominator when calculating a physician's or practitioner's percent of allowed charges that were primary care services for purposes of the PCIP.

8. Summary

In summary, we are proposing for CY 2015 to establish a separate payment under the PFS for complex chronic care management services furnished to patients with multiple complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, as discussed in section II.I.1. We are proposing the scope of these complex chronic care management services discussed in section II.I.2; the billing requirements for these services as discussed in section II.I.4; the AWV requirement as discussed in section II.I.5; the general supervision requirements as discussed in section II.I.6, and the PCIP denominator exclusion as discussed in section II.I.7.

We are seeking input from the public on, the standards required to provide these services as discussed in section II.I.3, and the work and PE that would be associated with these services.

We are making this proposal to establish codes and separate payment for complex chronic care management services in the context of the broader

multi-year strategy to appropriately recognize and value primary care and care management services. Should this proposal become final policy, it may be a short-term payment strategy that would be modified and/or revised to be consistent with broader primary care, and care management and coordination services if the agency decides to pursue payment for a broader set of management and coordination services in future rulemaking. We also note that as we consider a final policy, we would assess the potential impact of the policy on our current programs and demonstrations designed to improve payment for, and encourage long-term investment in, care management services. Likewise, to assure that there are not duplicate payments for delivery of care management services, we would consider whether such payments are appropriate for providers participating in other programs and demonstrations.

J. Chiropractors Billing for Evaluation and Management Services

Section 1861(r)(5) of the Act includes chiropractors in its definition of ''physician'' with language limiting chiropractors to ''treatment by means of manual manipulation of the spine (to correct a subluxation).'' Specifically, the Act says:

> The term ''physician,'' when used in connection with the performance of any function or actions means . . . a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services) and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform the State or jurisdiction in which such treatment is provided.

The statute, thus, limits chiropractic coverage to treatment of subluxation of the spine. Our interpretation of this language allows payment to chiropractors for chiropractic manual manipulation to correct a subluxation of the spine. Specifically, we provide for payment of the following codes listed in the chiropractic section of the CPT Manual.

98940—Chiropractic manipulation treatment (CMT), spinal, 1–2 regions
98941—CMT spinal, 3–4 regions
98942—CMT spinal, 5 regions

(CPT includes an additional CPT code 98943—CMT extraspinal 1 or more regions for which Medicare does not cover as it is not a spinal manipulation.)

Section 240.1.2 of the IOM 100–02 includes requirements that must be met to demonstrate that these services are necessary, using either x-ray or physical examination. In addition, it includes documentation requirements for initial and subsequent visits. These include a history and physical exam.

According to the CPT manual, the codes for CMT describe services including a ''pre-manipulative patient assessment,'' which is consistent with the history and physical exam requirement discussed above. In determining the relative value assigned to the CMT services we include this pre-manipulative patient assessment.

These chiropractic codes have a global surgery indicator of 0, meaning that we do not pay separately for services provided on the same day and related to the same service. The CPT manual notes that separate E/M services can be reported with a -25 modifier ''if the patient's condition requires a significant, separately identified E/M service above and beyond the usual preservice and postservice work associated with the procedures.'' It goes on to note that a separate diagnosis is not required.

We currently do not allow payment for E/M services to chiropractors as we have not identified an E/M service that would be related to treatment of subluxation of the spine, which is the statutory requirement, beyond the preservice and postservice work associated with the CMT. We have believed that the assessments included in the CMT codes accurately capture the E/M that would typically be furnished by chiropractors in furnishing CMT services.

Questions have arisen as to whether it would be appropriate to allow chiropractors to furnish and bill Medicare for E/M services, especially in light of the CPT language regarding the reporting of a separate E/M service on the same day using a -25 modifier. We would note that CPT codes are the HIPPA compliant code set. Their use is not limited to Medicare, and other insurers may not limit chiropractic coverage to manual manipulation to correct subluxation of the spine. We are seeking comment to assess whether there are situations in which E/M services that are not included in the CMT codes, but would meet the statutory requirements for chiropractor services, would be appropriate. We are not proposing to pay chiropractors for E/M services in CY 2014. If after receiving and analyzing public comment we determine that it would be appropriate to modify our policy with respect to chiropractors and E/M services, we would do so in future rulemaking.

Specifically, we are seeking comments on the following questions:

- Are there situations where a chiropractor would furnish E/M services that are with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) that are not included within the definition of the CMT codes? Specifically, we are seeking information on the situations, the services that would be provided, and the E/M codes that would be billed.
- Would such a policy expand access to chiropractic services for Medicare beneficiaries? Are there other benefits that would accrue?
- If payment were to be allowed for E/M services, which codes would be appropriate to report chiropractic E/M services? For services provided in an office, would it be appropriate to allow billing of all five office E/M codes for new or existing patient as appropriate? Should one or a set of codes be created specifically for chiropractic E/M services similar to those for therapy evaluations or ophthalmic evaluations? With what frequency should chiropractors be allowed to bill E/M services?
- What would justify E/M services beyond those included in CMT codes? Should they be allowed on every treatment day or only at the onset of treatment?
- Are these E/M services ones that are already being furnished by another physician or other practitioner? If these are not services currently covered by Medicare, what volume could be expected?

III. Other Provisions of the Proposed Regulations

A. Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage

1. Statutory Authority and Background

This proposed rule would revise certain Medicare regulations currently codified in § 405.201 through 405.214, and § 411.15(o) relating to coverage of the costs of routine items and services in Category A Investigational device exemption (IDE) studies and trials, and coverage of the costs of Category B, investigational devices and the costs of routine items and services in Category B investigational device exemption (IDE) studies and trials. It is based on section 1862(m) of the Act, which, among other things, authorizes the Secretary to establish criteria to ensure that studies and trials of Category A devices conform to appropriate scientific and ethical

standards. We are proposing to establish those criteria that ensure that studies and trials of Category A devices conform to appropriate scientific and ethical standards. We are also proposing, based on our rulemaking authority in section 1871 of the Act, to extend the same criteria proposed for Category A IDE studies and trials to Category B IDE studies and trials. Our proposed rules are necessary to carry out the administration of the insurance program under Title XVIII of the Act). Finally, to ensure that coverage of items and services in IDE studies and trials is uniform across Medicare administrative regions, we are proposing that IDE coverage decisions will be made by CMS centrally.

On September 8, 1995, the FDA and CMS (then known as HCFA) entered into an interagency agreement in which the FDA agreed to categorize investigational device exemptions (IDEs) for purposes of Medicare coverage. The process identified in this interagency agreement is reflected in a September 19, 1995 final rule (60 FR 48417). The September 19, 1995 rule described two FDA device categories: (1) Category A devices were described as experimental/investigational devices; and (2) Category B devices were described as nonexperimental/investigational devices.

a. Coverage of IDE—Costs of Routine Items, Services, and Devices

The September 19, 1995 rule created a path to Medicare coverage under certain circumstances for Category B investigational devices and the costs of routine items and services in IDE studies and trials. The IDE coverage policy gave Medicare beneficiaries the opportunity to have earlier access to new medical devices, but these determinations were made by local Medicare contractors sometimes on a claim-by-claim basis. Although the current IDE policy was a path to earlier access to certain devices and the costs of routine items and services, we were also hearing that the IDE coverage approval process was burdensome and created national variability that made it difficult for study sponsors to conduct national IDE studies.

As we evaluated the IDE review and approval process we heard and sought out feedback from stakeholders (for example, manufacturers, study sponsors, and hospitals). Most of the stakeholders told us that obtaining coverage of the device and the costs of routine items and services was inefficient; that each Medicare contractor has different processes to review IDE devices and studies. It also became apparent that the lack of centralization led to inconsistent IDE coverage across the Medicare contractors. These factors contributed to some reluctance to enroll Medicare beneficiaries in IDE studies.

We also requested feedback from the Medicare local contractors. We found that the Medicare contractors reviewed pertinent available evidence and the FDA-approved IDE study protocol as factors in their decision-making process. Reviewing all of the information related to the IDE device and the FDA-approved study was a way to ensure that the device, as used, is reasonable and necessary for the Medicare beneficiary and furnished in a setting appropriate to the patient's medical needs. While each contractor's process was appropriate, they were in practice slightly different from contractor to contractor; and in most cases duplicative. Furthermore, we found that local Medicare contractors were applying varying levels of scrutiny in reviewing IDE devices and the costs of routine items and services within IDE studies. Most contractors reviewed IDE study protocols extensively, while other contractors may have reviewed them less extensively.

2. Proposals

We are proposing a transparent, centralized review process that would be more efficient by reducing the burden for stakeholders interested in conducting nationwide trials. Once the IDE coverage process is centralized, there would be a single entity making the IDE coverage decision. This enhances administrative efficiency by eliminating the need for duplicative reviews by Medicare local contractors and the submission of duplicated coverage requests to different contractors by stakeholders. We believe that a centralized review process would not significantly reduce the number of IDE devices currently covered; but we are specifically requesting public to comment on this issue. Changing the review and decision of IDE coverage to a centralized review process in no way changes any beneficiary appeal rights.

a. Category A IDE Devices

In 2003, section 731(b) of the Prescription Drug, Improvement, and Modernization Act (MMA) provided that the Secretary could not exclude coverage for certain routine care costs in IDE studies and trials of Category A devices, provided to beneficiaries under section 1862(a)(1)(A) of the Act. A Category A IDE device is a device for which the initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective. In addition, the Secretary was given the authority to ensure that any Category A IDE device study conform to appropriate scientific and ethical standards (section 1862(m)(1) of the Act). While the Congress gave the Secretary the authority to determine the scope of routine care costs, the Congress did not authorize or establish coverage for the Category A device itself. Therefore, we are not proposing any changes to coverage of the Category A IDE device. Category A devices would continue to be noncovered under section 1862(a)(1)(A) of the Act.

The Congress has expressly authorized the Secretary to establish criteria to ensure that any Category A IDE device study conform to appropriate scientific and ethical standards. (For more information, see section 1862(m)(2)(B) of the Act.) In the November 15, 2004 conforming final rule (69 FR 66420), we finalized a regulatory provision at § 405.207(b)(2) requiring Category A IDE devices be furnished in conjunction with an FDA-approved clinical study and that the study standards would be defined through the national coverage determination (NCD) process. Rather than establish standards through the NCD process, we would specify the study standards in this proposed rule. We believe the Congress gave the Secretary the authority to create appropriate scientific and ethical standards because of their importance in protecting for Medicare beneficiaries.

The use of standards is essential to protecting Medicare study participants in category A trials. Studies that have high scientific and ethical standards lead to generalizable and reliable knowledge for Medicare providers, practitioners and beneficiaries.

We believe that minimum standards are needed for IDE studies and trials for which Medicare coverage of devices or routine items and services is provided to ensure that Medicare beneficiaries who volunteer to participate in studies are protected and that the study design is appropriate to answer questions of importance to Medicare and its beneficiaries. Although an item or service may be considered ''reasonable and necessary'' when used by a clinician for the benefit of an individual patient, it may not necessarily be reasonable and necessary when used in the context of an IDE study or trial. The use of such an item or service in an IDE study or trial may expose the study participants to increased risks that must be balanced by other factors, including the likelihood that the study would add important information to the body of

medical knowledge. There are numerous studies that may be considered ''scientifically valid,'' but are of little benefit to patients or to the Medicare program.

It is essential that CMS-approved IDE studies or trials serve the best interests of Medicare beneficiaries. We believe, in concert with other federal agencies, that appropriate study design is critical to ensure that not only are participants in research studies exposed to the least risk possible, but also to ensure that the results from the study would be useful in improving healthcare delivery. Scientifically and ethically flawed studies will not produce valid results, exposing Medicare beneficiaries to unnecessary risk; and wasting time and resources for all involved.

We are proposing 13 standards that Category A IDE studies must meet in order for the costs of routine care items and services to be coverable. The first four and the seventh proposed standards embody ethical values. The fifth and sixth proposed standards were developed in response to reports of egregious misconduct in the past in endeavors to conduct clinical research by placing individuals at the risk of harm for the good of others. Both the independent review of protocols and informed consent by study participants are warranted to provide accountability to the public that the conduct of the study is not compromised by potential conflicts of interest on the part of investigators, and the study subject's autonomy is respected.

The IDE study and trial standards that we are proposing are as follows:

- The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.
- The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The study results are not anticipated to unjustifiably duplicate existing knowledge.
- The study design is methodologically appropriate and the anticipated number of enrolled subjects is appropriate to answer the research question(s) being asked in the study.
- The study is sponsored by an organization or individual capable of completing it successfully.
- The study is in compliance with all applicable federal regulations concerning the protection of human subjects found at 45 CFR part 46.
- All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.
- The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- Where appropriate, the clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.
- The study is registered on the *ClinicalTrials.gov* Web site and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject.
- The study protocol specifies the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. The release should be hastened if the study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (*http://www.icmje.org*). However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
- The study protocol explicitly discusses subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the study. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- The study protocol explicitly discusses how the results are or are not expected to be generalizable to subsections of the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

In proposed § 405.212(a)(1) through (7), we would set forth scientific standards for IDE studies or trials in which providers, practitioners, suppliers or beneficiaries are requesting payment for items or services provided to Medicare beneficiaries participating in the IDE study or trial.

While most studies are undertaken only after a detailed protocol has been developed, some are not. The protocol is the primary source of knowledge on the proposed design and management of the study. Without this document, reviewers and funding entities are unable to ascertain the quality and validity of the study. The exercise of committing to paper all the aspects of the study is crucial to ensuring that all potential concerns have been addressed. It is impossible to evaluate the adequacy of trial design without a written protocol. We do not propose to define the content of that protocol. Numerous federal agencies and other scientific entities have done that. However, in proposed § 405.212(a)(8) we would specify that all IDE studies or trials must have a written protocol addressing the Medicare standards.

In proposed § 405.212(a)(9), we would specify the ''therapeutic intent'' requirement. We are proposing a standard that limits IDE studies to those that do not exclusively test toxicity or disease pathophysiology in healthy individuals but also have a therapeutic outcome. However, the study may exclusively test toxicity or disease pathophysiology, if the disease or condition being studied must be life-threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options or is severely debilitating as defined in 21 CFR 312.81(b). In proposed § 405.212(a)(10), we would specify the standard that requires that IDE studies and trials that Medicare supports be registered on *ClinicalTrials.gov site*. The National Institutes of Health/National Library of Medicine (NIH/NLM) established a clinical trials registry (*ClinicalTrials.gov*) to meet the requirement of the 1997 Food and Drug Administration Modernization Act. After a thorough review of the NIH/NLM *ClinicalTrials.gov* Web site, we believe that all studies covered under this policy should be registered in this registry prior to enrollment of the first subject.

Registration into *ClinicalTrials.gov* assures that beneficiaries would have pertinent information about and IDE study or trial Medicare supports—an essential component of transparency to

facilitate patient-provider informed decision-making. The World Health Organization and International Committee of Medical Journal Editors (WHO/ICMJE) data elements are the required data elements in this registry. Information about this registry may be obtained at *http://www.clinicaltrials.gov/*. We believe that registration serves the public's desire to obtain information about the studies that their Medicare premiums and tax dollars support.

In proposed § 405.212(a)(11), we would address the issue of dissemination of the IDE study or trial findings. We believe that it is imperative that the results of IDE studies and trials for which Medicare has made payment of any clinical costs be made available to the public regardless of the outcomes. If trial results are not published, they do not add to the clinical evidence base and cannot be used for medical decision-making. For this standard, we are suggesting that the study protocol provides a discussion of the publication/dissemination plan of the study findings.

In proposed § 405.212(a)(12), we would focus on the issue of under-representation of specific demographic groups in U.S. clinical research studies. We want to support studies that allow Medicare beneficiaries to voluntarily participate in; and that add to the knowledge base about the use of the IDE device in the Medicare population, to ultimately improve the quality of care that Medicare beneficiaries receive. Well-designed studies have protocols that define the populations with the highest risk of having the disease or condition being studied. If data are not available that clearly demonstrate differences of clinical importance in subgroups defined by gender, race/ethnicity, age, or other relevant subpopulations, then the protocol must discuss the necessary steps to enroll appropriate numbers of these populations to ensure a valid analysis of the intervention effects. It is not our intention to require a specific enrollment of all subpopulations. However, it is, our intention that all covered study protocols address populations affected by the technology under investigation with special emphasis on minority and other groups that have experienced disparities in health care due to a lack of quality research data. If convincing evidence indicates that no differences exist between identified subgroups, that information should be noted in the protocol.

In proposed § 405.212(a)(13), we would specify the standard that requires that an IDE study or trial protocol explicitly discuss how the results are or are not expected to be generalizable to subsections of the Medicare population and to infer whether Medicare patients may benefit from the intervention. More often than not the published evidence does not include the Medicare population. We believe that unless there are clear data documenting that no important differences exist between the Medicare beneficiaries and the population studied, the study must discuss the enrollment of appropriate numbers representative of the Medicare population to ensure that the analysis of the results of the intervention may be applicable to Medicare beneficiaries.

In § 405.211, we are proposing that if the following two characteristics are also included met in addition to the criteria listed in § 405.212(a)(1) through (a)(13), we would automatically cover the costs of routine items and services in the Category A study or trial, and the costs of the investigation device and the routine items and services in a Category B study or trial as follows:

- The study is a pivotal study.
- The study has is a superiority study design.

In § 405.212, we propose a process by which Category A IDE studies will qualify for Medicare coverage of routine items and services provided in the studies. We propose that any interested party who seeks coverage in an IDE study may send us a request letter that describes the scope and nature of the IDE study, discussing each of the 15 standards in this policy.

b. Category B IDE Devices

Under our regulations, a nonexperimental/investigational (Category B) device was described as a device for which the underlying questions of safety and effectiveness has been resolved. In the absence of a NCD, Medicare coverage for Category B devices has been decided by Medicare contractors, subject to review under the claims review process at § 405.211(b). If the Category B device was covered, Medicare also covered the costs of items and services specific to the use of the device and furnished in conjunction with an FDA-approved clinical study.

Beyond Category A IDE studies, we believe that all investigational device studies wherein Medicare coverage is sought should conform to rigorous scientific and ethical standards. We believe that regardless of whether the device is categorized as an A or B the IDE study should meet the same scientific and ethical standards. Thus, we are proposing to require that Category B IDE trials must meet the same scientific and ethical standards.

c. Review and Approval (§ 405.212)

We are proposing a centralized IDE coverage review process for Category A and Category B IDEs. We believe the criteria § 405.212(a)(1) through (a)(13) are integral to coverage in any study that is Medicare-approved because it ensures that the IDE device is being furnished in a study with high levels of scientific and ethical integrity.

In addition, we propose to cover Category B IDE devices and the costs of routine care items and services furnished in an IDE study that meets the criteria proposed § 405.212(a) and the following additional criteria:

- The study is a pivotal study.
- The study has is a superiority study design.

As we review the IDE studies, we would look for reasonable assurance that enrolled Medicare beneficiary subjects will receive the best possible care and are protected when they are subjects in these IDE studies. The pivotal study and superiority study design criteria furnish assurances that the study results will be informative for beneficiary choices and medical decision-making in the non-trial settings where most care is actually furnished. We believe that their decisions are facilitated by trial designs that allow them to compare their options and determine which one is superior for the beneficiary. Non-inferiority trial designs (in contrast to superiority designs) only support more limited and thus less useful conclusions, that is, that the investigated device is no worse than the comparator treatment by some pre-specified margin.

Supporting materials may be submitted. The request would include the following information:

- The FDA approval letter.
- IDE study protocol.
- IRB approval letter(s).
- The *ClinicalTrials.gov* identifier

We propose that requests should be submitted via email to *clinicalstudynotification@cms.hhs.gov* or via hard copy to the following address:

Centers for Medicare & Medicaid Services, Center for Clinical Standards & Quality, Director, Coverage and Analysis Group, ATTN: Clinical Study Certification, Mailstop: S1–02–01, 7500 Security Blvd., Baltimore, MD 21244.

d. Notification

We propose that we would notify beneficiaries, providers, and practitioners of the IDE studies of all IDE devices eligible for coverage by

posting the IDE study title and *ClinicalTrials.gov* registry number on our Web site and publishing a list in the **Federal Register**.

e. Additional/Conforming Changes

In addition to the proposed changes in § 405.211 and § 405.212, we note the following changes:

• In § 405.201(b), Definitions, we would be revised the section by removing, revising and adding definitions. Some of the definitions that we are proposing to remove comprise factors that will allow stakeholders to understand the clinical study criteria for items and services furnished in an IDE study including the Category A and B device itself. Therefore, we proposing the following changes

++ Removal of the following definitions:

++ Class I, II, and III devices which refers to the different designations of FDA devices. These designations are not relevant to CMS coverage of an IDE device and routine items and services in an IDE study.

++ Post-market approval refers to a marketing application for a Class III device. Like class this is not relevant to whether CMS may cover an IDE device or routine items or services in an IDE study.

++ Adding the following definitions:

—*Clinicaltrials.gov* which refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. After a thorough review of the NIH/NLM *ClinicalTrials.gov* Web site, we believe that all studies covered under this policy should be registered in this registry. This is common practice in the research community. Studies and trials are now transparent—the study sites, investigator names, source of support, description of the study methods, and study results are open to the public, including Medicare beneficiaries. We believe that registration serves the public's desire to obtain information about the studies they may want to participate. This is a benefit to beneficiaries and their providers participating in IDE studies.

—Pivotal studies or trials, which refer to clinical investigations designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects. It may or may not be preceded by an early and/or a traditional feasibility study or trial.

—Routine care items and services, which refer to items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are furnished in either the experimental or the control arms of a clinical trial and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical trial. We note that noncoverage of a routine care item or services under an IDE trial in no way restricts a beneficiary's access to guaranteed Medicare benefits outside of an IDE trial.

—Superiority studies refer to studies or trials that are intended to demonstrate at some pre-specified level of confidence that the effect of an investigational treatment is superior to that of an active control by more than a pre-specified margin.

We are proposing the additions of the previously discussed definitions because we would use these factors in our decision to cover an investigational device and the costs of routine items and services in an IDE study.

• We are proposing to modify the following definitions:

++ The term Category A which was developed in cooperation with the FDA for the purposes of distinguishing those FDA classes under which investigational and non-investigational devices fall. A Category A IDE device is considered an experimental device; and therefore, deemed noncovered by Medicare standards.

++ Category A device would be defined as a device for which ''absolute risk'' of the device type has not been established (that is, the question of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

++ The term Category B which was developed in cooperation with the FDA for the purposes of distinguishing those FDA classes under which investigational and non-investigational devices fall. FDA assigns each device with an FDA-approved IDE to one of two categories. We propose to revise the definition of Category B (Nonexperimental/investigational) device to mean a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

++ Contractors mean Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare items and services. Currently, this is the definition refers to CMS's local Medicare Contractors. We propose to update the current definition in order for the definition to be accurate and consistent Agency-wide.

++ *IDE stands for investigational device exemption.* An FDA-approved IDE application permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

In § 405.203, FDA categorization of investigational devices, we are not proposing any changes. We have found that the interagency agreement between the FDA and CMS that supports the FDA categorization of devices to one of two categories for investigational purpose is widely accepted among device manufacturers. Therefore, to avoid future confusion by changing the categorization, we believe that maintaining this process continues to support the development of new health technologies and tools that practitioners and beneficiaries have access. It should be noted that neither the determination nor any re-evaluation made by FDA, nor the review determination made by CMS under § 405.211, would be considered coverage determinations that implicate the Part 426 NCD/LCD appeals process.

In § 405.207—

• In paragraph (a), we are not proposing any changes to our current noncoverage of Category A IDE devices. As stated previously, we continue to find that because initial questions of safety and effectiveness have not been resolved and the FDA is unsure of whether the device type can be safe and effective, experimental/investigational (Category A) devices are not reasonable and necessary under section 1862(a)(1)(A) of the Act; and

• Paragraph (b) currently states that all Category A IDE studies and trials must meet the criteria established through the NCD process. Because we are proposing scientific and ethical standards, we no longer need to establish the IDE study criteria through the NCD process; and therefore, we are proposing to delete the NCD process requirement. We are also proposing to remove the following statement from § 405.207(b)(2) that states ''If the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-

threatening disease or condition'' because it is no longer applicable. We are not proposing changes to § 405.207(b)(1) or (b)(3).

In §§ 405.205, 405.207, 405.209, and 405.211, we propose to retain the current explanation of coverage and payment for non-experimental/investigational devices.

For § 405.213, Re-evaluation of a device categorization, we are not proposing any changes to this section because we believe that maintaining this process continues to support the development of new health technologies and tools that practitioners and beneficiaries have access.

We are proposing to retain the protections in § 405.215, Confidential Commercial and Trade Secret Information, without modification. We note that section 502(c) of the Act broadly prohibits the disclosure of trade secret and confidential commercial or financial information—information exempt from public disclosure by the Freedom of Information Act (FOIA) 5 U.S.C. 552(b)(4) outside the Department. This prohibition is found in the devices and regulatory inspections provisions of the Act, and is not limited to device-related information. This disclosure prohibition also applies to information reported or otherwise obtained by the Department during inspection activities and other activities. This prohibition is interpreted to allow information sharing within the U.S. Department of Health and Human Services only.

In § 411.15(o)(2), Experimental or investigational device exclusions, we propose to revise the requirement to specify that the exclusions under this section include experimental or investigational devices, except for certain devices furnished in accordance with the CMS IDE study and trial standards established in § 405.21l. We are proposing this change to be consistent with the IDE study characteristics.

B. Ultrasound Screening for Abdominal Aortic Aneurysms

1. Background and Statutory Authority

Section 1861(s)(2)(AA) of the Act authorizes Medicare coverage under Part B of ultrasound screening for abdominal aortic aneurysms (''AAA screening''), as defined in section 1861(bbb) of the Act. Our implementing regulations for AAA screening are at § 410.19. AAA screening is covered for a beneficiary that meets certain criteria including that he or she must receive a referral during the initial preventive physical examination (IPPE) and has not previously had an AAA screening covered under the Medicare program. The IPPE, as described in section 1861(ww) of the Act (and regulations at § 410.16), includes a time restriction and must be furnished not more than one year after the effective date of the beneficiary's first Part B coverage period (see section 1862(a)(1)(K) of the Act). This time limitation for the IPPE effectively reduces a Medicare beneficiary's ability to obtain a referral for AAA screening.

Section 1834(n) of the Act, added by section 4105 of the Affordable Care Act, grants the Secretary the discretion and authority to modify coverage of certain preventive services identified in section 1861(ddd)(3) of the Act, which in turn cross-references section 1861(ww)(2) of the Act (including AAA screening at section 1861(ww)(2)(L). The Secretary may modify coverage to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force (USPSTF) per section 1834(n)(1)(A) of the Act. In 2005, the USPSTF recommended ''one-time screening for [AAA] by ultrasonography in men ages 65 through 75 who have ever smoked. (Grade: B Recommendation)'' (Screening for Abdominal Aortic Aneurysm: Recommendation Statement. *http://www.uspreventiveservicestaskforce.org/uspstf05/aaascr/aaars.htm*). The USPSTF recommendation does not include a time limit with respect to the referral for this test.

2. Provisions of the Proposed Regulations

We are proposing to exercise our discretion and authority under section 1834(n) of the Act to modify coverage of AAA screening consistent with the recommendations of the USPSTF to eliminate the one-year time limit with respect to the referral for this service. This proposed modification would allow coverage of AAA screening for eligible beneficiaries without requiring them to receive a referral as part of the IPPE. Specifically for purposes of coverage of AAA screening, we propose to modify the definition of ''eligible beneficiary'' in § 410.19(a) by removing paragraph (a)(1), of this definition, and redesignating paragraphs (a)(2) and (a)(3) of this definition as paragraphs (a)(1) and (a)(2), respectively.

The IPPE is a one-time benefit available to beneficiaries under Part B that receive the IPPE not more than one year after the effective date of the beneficiary's first Medicare Part B coverage period. Many beneficiaries were either not eligible to receive an IPPE (which did not become effective until January 1, 2005) or may not have taken advantage of the IPPE when they were eligible, limiting access to AAA screening. We believe that our proposed modification is consistent with current USPSTF recommendations for one-time screening and allows for expanded access to this important preventive service. We invite public comment on this proposal.

C. Colorectal Cancer Screening: Modification to Coverage of Screening Fecal Occult Blood Tests

1. Background and Statutory Authority

Sections 1861(s)(2)(R) and 1861(pp)(1) of the Act authorize Medicare coverage of colorectal cancer screening. The statute authorizes coverage of screening fecal occult blood tests (FOBT), screening flexible sigmoidoscopies, screening colonoscopies, and other tests determined to be appropriate, subject to certain frequency and payment limits. Section 410.37(b) (condition for coverage of screening FOBT) specifies that Medicare Part B pays for screening FOBT if ordered in writing by the beneficiary's attending physician. For purposes of § 410.37, ''attending physician'' is defined as ''a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible using the results of any examination performed in the overall management of the beneficiary's specific medical problem.''

The coverage provisions for FOBT screening were established in 1997 and effective on January 1, 1998 (62 FR 59048, October 31, 1997). In the preamble to that final rule, we stated that the requirement for a written order from the attending physician was intended to make certain that beneficiaries receive appropriate preventive counseling about the implications and possible results of having these examinations performed (62 FR 59081).

Since then, Medicare coverage of preventive services has expanded to include, among other things, coverage of an annual wellness visit (as defined in § 410.15). The annual wellness visit includes provisions for furnishing personalized health advice and appropriate referrals. In addition to physicians, the annual wellness visit can be furnished by certain nonphysician practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists.

Additionally, § 410.32 provides coverage and payment rules for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic

tests. Section 410.32(a)(2) states: ''Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.''

2. Proposed Revisions

We are proposing to revise § 410.37(b), ''Condition for coverage of screening fecal-occult blood tests,'' to allow an attending physician, physician assistant, nurse practitioner, or clinical nurse specialist to furnish written orders for screening FOBT. These proposed modifications would allow for expanded coverage and access to screening FOBT, particularly in rural areas. We invite public comment on this proposal. In addition, we are seeking public comment regarding whether a practitioner permitted to order a screening FOBT must be the beneficiary's attending practitioner as described earlier.

D. Ambulance Fee Schedule

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

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, enacted on July 15, 2008) (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.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010, and before January 1, 2011. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386, 73625), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 106(a) of the Medicare and Medicaid Extenders Act of 2010 (Pub. L.111–309, enacted December 15, 2010) (MMEA) again amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2011, and before January 1, 2012. In the CY 2012 End-Stage Renal Disease Prospective Payment System (ESRD PPS) final rule (76 FR 70228, 70284 through 70285, and 70315), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 306(a) of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCA) (Pub. L. 112–78, enacted on December 23, 2011) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through February 29, 2012; and section 3007(a) of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, enacted on February 22, 2012) (MCTRJCA) further amended section 1834(l)(13)(A) of the Act to extend these payment add-ons through December 31, 2012. Thus, these payment add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2012 and before January 1, 2013. In the CY 2013 PFS final rule (77 FR 69139, 69368), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 604(a) of the ATRA amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through December 31, 2013. Thus, these payment add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2013 and before January 1, 2014. Thus, we propose to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

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

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of certain rural areas for payment of air ambulance services. This section originally specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385, 73386, and 73625 through 73626), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. In the CY 2012 ESRD PPS final rule (76 FR 70284, 70285, and 70315), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 306(b) of the TPTCCA amended section 146(b)(1) of MIPPA to extend this provision through February 29, 2012; and section 3007(b) of the MCTRJCA further amended section 146(b)(1) of MIPPA to extend this provision through December 31, 2012. In the CY 2013 PFS final rule (77 FR 69139, 69140, and 69368), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 604(b) of the ATRA amended section 146(b)(1) of MIPPA to extend this provision through June 30, 2013. Thus, we propose to revise § 414.610(h) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the ''rural'' indicator on the ZIP Code file for air ambulance services through June 30, 2013.

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

Section 414 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).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, in the CY 2012 ESRD PPS final rule (76 FR 70284, 70285 and 70315), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 306(c) of the TPTCCA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through February 29, 2012; and section 3007(c) of the MCTRJCA further amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2012. In the CY 2013 PFS final rule with comment period (77 FR 69140, 69368), we revised § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements.

Subsequently, section 604(c) of the ATRA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2013. 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 on or after January 1, 2013 and before January 1, 2014 where transportation originates in a qualified rural area. Accordingly, we propose to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

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.

This statutory requirement is self-implementing. This provision requires a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2013, and does not require any substantive exercise of discretion on the part of the Secretary.

4. Addition of Section 1834(l)(15) of the Act

Section 637 of the ATRA, which added section 1834(l)(15) of the Act, specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. We are proposing to revise § 414.610 by adding paragraph (c)(8) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for the ambulance services described in section 637 of the ATRA furnished on or after October 1, 2013, the fee schedule amount otherwise applicable (both base rate and mileage) will be reduced by 10 percent. For further information regarding application of this mandated rate decrease, please see CR 8269.

5. Studies of Ambulance Costs

Section 604(d)(1) of the ATRA provides that the Secretary shall conduct the following studies:

(A) A study that analyzes data on existing cost reports for ambulance services furnished by hospitals and critical access hospitals, including variation by characteristics of such providers of services, with a Report to Congress on such study due no later than October 1, 2013; and

(B) A study of the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(l) of the Act and in preparing for future reform of such payment system, with a Report to Congress due on such study no later than July 1, 2014.

Further, in conducting the study under paragraph (B) above, section 604(d)(2) of the ATRA directs the Secretary to:

- Consult with industry on the design of such cost collection efforts;
- Explore the use of cost surveys and cost reports to collect appropriate cost data and the periodicity of such cost data collection;
- Examine the feasibility of developing a standard cost reporting tool for providers of services and suppliers of ground ambulance services; and
- Examine the ability to furnish such cost data by various types of ambulance providers of services and suppliers, especially by rural and super-rural providers of services and suppliers.

As noted above, in conducting the study under section 604(d)(1) of the ATRA described in paragraph (B) above, the Secretary is required to consult with industry on the design of such cost collection efforts (see section 604(d)(2)(A) of the ATRA). We are using this proposed rule as the instrument to collect information, comments, and ideas from the industry on the design of such cost collection efforts as described above, and on the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(l) of the Act and in preparing for future reform of such payment system. We therefore invite public comment on these issues

as part of the study we are conducting under section 604(d)(1)(B) of the ATRA.

E. Proposals Regarding the Clinical Laboratory Fee Schedule

1. Background on the Clinical Laboratory Fee Schedule

Under Medicare Part B, clinical diagnostic laboratory tests furnished on or after July 1, 1984, in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients and nonpatients currently are paid on the basis of the Clinical Laboratory Fee Schedule (CLFS), with limited exceptions. For each Healthcare Common Procedure Coding System (HCPCS) code, payment is the lesser of:

- The amount of charges billed for the test;
- The fee schedule amount for the State or a local geographic area; or
- A national limitation amount (NLA) (section 1833(a)(1)(D)(i), (a)(2)(D)(i), (h)(1), and (h)(4)(B) of the Act). The NLA for a clinical diagnostic laboratory test performed after December 31, 1997 is equal to 74 percent of the median of all fee schedules established for that test for that laboratory setting or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established (section 1833(h)(4)(B)(viii) of the Act).

Currently, we update the CLFS amounts annually to reflect changes in the Consumer Price Index for all Urban Consumers (U.S. city average) (CPI–U) and apply a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). In the past, we also implemented other adjustments or did not apply the change in the CPI–U to the CLFS in accordance with statutory mandates. For example, under section 1833(h)(2)(A)(i) of the Act, we were required to subtract 0.5 percentage points from the CPI–U adjustment for 2009 and 2010. We do not otherwise update or change the CLFS.

For any clinical diagnostic laboratory tests where a new or substantially revised HCPCS code is assigned on or after January 1, 2005, we determine the basis for, and amount of, payment for these clinical diagnostic laboratory tests (see section 1833(h)(8) of the Act and 42 CFR 414.500 through 414.509). Once established, however, in most cases, we only have the opportunity to reconsider the basis and/or amount of payment for new tests for one additional year after the basis or payment is initially set. Once the reconsideration process is complete, payment is not further adjusted (except by a change in the CPI–U, the productivity adjustment, and any other adjustments required by statute), regardless of any shift in the actual costs incurred to perform the test.

This lack of an established mechanism to adjust payment amounts is unique among the Medicare payment schedules and systems. Generally, fee schedules and prospective payment systems are evaluated each year to reflect the changing mix of services provided under that system or schedule and then the system or schedule is adjusted to maintain budget neutrality. Since there is currently no process to make such adjustments for the CLFS, payment amounts are essentially locked in place and do not change when the cost of the test changes. As discussed below, in this proposed rule, we are proposing to implement a process to adjust payment amounts based on changes in technology.

2. Proposals Regarding Technological Changes Under Section 1833(h)(2)(A)(i) of the Act

a. Background on Technological Changes

There has been a significant amount of technological change in the clinical laboratory area since the implementation of the CLFS, which has resulted in the increased use of point-of-care testing, brand new tests being developed, and the proliferation of laboratory-developed tests. The Institute of Medicine (IOM) dedicated a chapter of its 2000 report ''Medicare Laboratory Payment Policy: Now and in the Future'' to discussing trends in laboratory technology. The report noted rapid and dramatic innovation in the laboratory sector since the 1980s and remarkable growth in the range and complexity of available tests. The IOM concluded that the introduction of new tests, advances in equipment and testing techniques, and the proliferation of advanced information technology have all made testing more efficient and automated.

Technology has enabled a significant site-of-service shift for many laboratory tests from the laboratory environment to the point of health care delivery. This point-of-care testing has increased since the 1980s, when this type of testing first became available, mainly due to changes in technology which resulted in smaller, cheaper, and more portable test kits that are simple to use. For example, drug abuse testing has become readily available at the point of care. Point-of-care testing can be performed in various institutional and community settings but the main objective of such testing is to produce a result quickly, at the place where the patient is receiving care, such as at a physician's office or at a hospital bedside, to facilitate decisions about appropriate treatment.

There are also brand new technologies that did not exist when the CLFS was established, most notably genetic and genomic tests. This area of medicine evolved from the work of the Human Genome Project and subsequent research and development by both the federal government and private firms. The cost of sequencing a genome has dropped dramatically since the early inception of this technology in 2001 from more than $95 million per genome to approximately $5,700 in early 2013 (*http://www.genome.gov/pages/der/sequencing_cost.xlsx*). Early tests in this area were less likely to be covered by Medicare because they were either screening tests or tests for conditions found in the pediatric population. As this area has expanded over the past several decades, Medicare has taken on a more prominent role in payment for these services (see 77 FR 68994 through 69002 for a thorough discussion of how Medicare pays for these tests). We expect the number of codes and tests in this area to continue to grow as the technology evolves and more tests become available in the areas of pharmacogenomics, personalized and predictive medicine, and companion diagnostics.

We also note the growth in laboratory-developed tests (LDTs) over the years. These proprietary tests are developed by laboratories, which then offer the service of providing the test. Some of the most advanced laboratory tests currently being performed are LDTs which use sophisticated proprietary technology. Many LDTs do not have their own codes; instead, they are billed using unlisted codes for which contractors establish a payment amount. Other LDTs were billed to Medicare using ''stacking codes,'' where a laboratory submits a code for each step of the testing process; however, these ''stacking codes'' were eliminated at the end of 2012 for molecular pathology tests and replaced with 114 new test-specific codes. These payment processes provide us with limited information about the technology used to perform these tests. However, we know that the number of LDTs has been growing over the years and multiple laboratories have developed ways to perform the same test. Further, our recent experience with using a gap filling methodology to price molecular pathology tests, which are often LDTs, has shown that the costs of performing these tests have decreased since contractors initially established

payment amounts for the tests, or compared to the code stack previously billed. Our experience with gap filling molecular pathology tests has also shown that there is wide variation in the cost of performing the same test by different laboratories.

We believe that, given the technological changes that have occurred in the laboratory industry over the past several decades and the growth in the number of clinical laboratory tests (CMS has added approximately 800 new test codes to the CLFS since its inception), it would be appropriate to establish a process to reconsider payment amounts on the CLFS to take into account increased efficiency, changes in laboratory personnel and supplies necessary to conduct a test, changes in sites of service, and other changes driven by technological advances.

Section 1833(h)(2)(A)(i) of the Act requires the Secretary to set the fee schedules for clinical laboratory tests ''for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to [the multi-factor productivity adjustment], [the change in the CPI–U] and *subject to such other adjustments as the Secretary determines are justified by technological changes''* (emphasis added). Under this authority, we are proposing a process under which we will systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount.

b. Proposed Definition of Technological Changes

We are proposing to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used. Changes in technology could result in changes to, among other things, the resources required to perform the test (such as the type, volume, or number of supplies or reagents required), the laboratory personnel required to perform the test, and/or the frequency of testing, volume of testing, or site of service (for example, a shift in service site from a specialty laboratory to a physician's office). We believe this broad definition would capture all of the technological changes that could impact the resource inputs for various tests on the CLFS. As discussed below, the technological changes for a specific test would be discussed in the proposed rule in which we are proposing to adjust the payment amount for that test, and we would seek public comment on our determination of the technological changes and the payment adjustment.

c. Proposed Process

We are proposing that, each year, we would review certain codes on the CLFS, as described in the next section, to determine whether we believe that payment for these codes should be adjusted due to technological changes. For those codes where we determine that payment adjustments should be made, beginning with the CY 2015 PFS proposed rule, we would identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes.

We believe such adjustments could be made both to increase fee schedule amounts (for example, in situations where new high cost technologies are employed), and to provide for reductions in existing amounts (for example in situations where technology reduces costs through increased efficiencies). We expect that most payment amounts will decrease due to the changes in technology that have occurred over the years since the payment amounts were established and the general downward trend of costs once technology has had an opportunity to diffuse. A key goal in establishing this review process is to ensure payment accuracy after technological changes; thus payment rates could increase or decrease as a result of these reviews.

Under our proposed process, we would also list codes that we reviewed but for which there was insufficient information to support or establish an adjustment to the payment amount due to technological changes. We would solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information. We expect that we would finalize any payment adjustments in the PFS final rule, beginning with the CY 2015 PFS final rule. We are proposing that the CPI–U and multi-factor productivity adjustments would be applied after we establish the new payment amount through our usual instruction process.

We believe that this proposed process would best allow for the greatest amount of transparency in review and the most structured and consistent opportunity for the public to provide input into the process. We are soliciting comment on these proposals.

d. Proposed Identification and Prioritization of Codes to be Reviewed

We are proposing to review all codes currently on the CLFS. We are proposing to start our review by examining the codes that have been on the CLFS the longest and then work our way forward, over multiple years, until we have reviewed all of the codes on the CLFS. We believe that the payment amounts for codes that have been on the CLFS the longest amount of time would be most affected by changes in technology because, in general, technology is most expensive earliest in its life cycle but decreases in cost as the technology matures and diffuses. If during the course of reviewing these individual codes we find that there are additional, newer codes that are clinically and/or technologically similar, we are proposing to consider them for review at the same time as we review the older codes because we expect we would have the same or similar justifications for making payment adjustments to those codes. We intend to review these codes as quickly as possible but we believe there would be a significant administrative burden associated with such a comprehensive review of the 1,250 codes on the CLFS. We are estimating that it would take at least 5 years to review all of the existing codes on the CLFS.

Once we have completed our review of the codes currently on the CLFS and made any adjustments necessary due to technological changes, we are proposing to review codes added to the CLFS after 2015 that have been on the CLFS for at least 5 years. We would also review codes again that have not been reviewed in the previous 5 years, as time and resources allow. We believe that tests that are less than 5 years old are likely still in their technological infancy and enough time would not have passed to adequately assess any change in technology for those services. Similarly, for previously reviewed codes, we believe that technology likely would not have changed dramatically in less than 5 years. We are soliciting public comment on how to prioritize these codes, which we expect to address in future rulemaking on this issue.

After the initial review of the codes currently on the CLFS, we are also proposing to allow the public to nominate additional codes for review, including those that had been previously reviewed for technological change. We are proposing that the public may nominate only codes that have been on the CLFS for at least 5 years and that have not been reviewed in the previous 5 years. Further, we are

proposing that the nomination must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery. We would then consider these nominations and, in the **Federal Register** the following year, either propose a payment change based on technological changes or explain why we think such a change is not warranted at that time.

We are proposing to codify the proposed process at 42 CFR 414.511.

We are seeking public comment on these proposals. We also are seeking comment on alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Finally, we are soliciting comment on general trends in technology change in the laboratory industry and the health care sector in general.

3. Proposed Changes in the CY 2014 OPPS/ASC Proposed Rule

In the CY 2014 OPPS/ASC proposed rule, CMS is proposing to package payment for certain clinical diagnostic laboratory tests into the base payment for the Ambulatory Payment Classification (APC). For details on this proposal, please see the ''Proposed Changes to Packaged Items and Services'' section of the CY 2014 OPPS/ASC proposed rule. Comments on the OPPS proposal should be made to the CY 2014 OPPS/ASC proposed rule. Comments on the proposals in this rule should be made to the CY 2014 PFS proposed rule.

F. Liability for Overpayments to or on Behalf of Individuals Including Payments to Providers or Other Persons

1. Background and Statutory Authority

CMS waives recovery of overpayments in certain situations for claims based fee-for-service provider, supplier or beneficiary overpayments in accordance with section 1870 of the Act. Section 1870(b) and (c) of the Act provide a waiver of recovery of provider, supplier or beneficiary overpayments under certain presumptions within a specified timeframe. Section 1870(b) and (c) of the Act allow the Secretary to reduce the specified time period to not less than one year if the Secretary finds that such a reduction is consistent with the objectives of the Medicare program. Section 638 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013) changed the timeframes associated with section 1870(b) and (c) of the Act.

Section 1870(b) of the Act provides for the waiver of recovery of an overpayment to a provider of services (hereinafter, ''provider'') or other person whenever that provider or other person is ''without fault'' in incurring the overpayment. For purposes of section 1870 of the Act and this proposed rule, the term ''other person'' includes practitioners, physicians, and other suppliers.

Section 1870(b) of the Act also establishes circumstances under which a provider or other person is presumed for administrative purposes to be ''without fault'' for an overpayment. If an overpayment is determined after a specified period of time, a provider or other person is presumed to be ''without fault.'' This presumption is negated, however, if there is evidence to show that the provider or other person was responsible for causing the overpayment.

Section 1870(c) of the Act provides for the waiver of recovery of an overpayment to an individual whenever the individual is ''without fault'' in incurring the overpayment, and recovery would either defeat the purpose of the Social Security or Medicare programs or would be ''against equity and good conscience.''

Section 1870(c) of the Act also establishes circumstances under which recovery of an overpayment for an individual is presumed to be ''against equity and good conscience.'' After a specified period of time, recovery of certain overpayments from individuals who are ''without fault'' is presumed ''against equity and good conscience.'' The overpayments addressed by this provision are payments for items or services for which payment may not be made because of the prohibitions found in section 1862(a)(1) or (a)(9) of the Act. Sections 1862(a)(1) and (a)(9) prohibit payment for, among other things, items and services that are not reasonable and necessary or that are for custodial care.

Section 638 of the ATRA amended the timeframe specified in section 1870(b) of the Act ''without fault'' presumption from 3 to 5 years so that the presumption of ''without fault'' only applies if the Medicare claims based fee-for-service overpayment determination for a provider or other person is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid. Likewise, section 638 of the ATRA amended the timeframe in section 1870(c) of the Act so that the presumption for ''against equity and good conscience'' for certain types of denials for an individual who is ''without fault'' only applies if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which notice of such payment was sent to such individual.

These ATRA changes do not affect or change CMS' claims reopening regulation at § 405.980. Specifically, we retain our authority to reopen claims for any reason within one year, for good cause within 4 years, and at any time for fraud or similar fault.

2. Provisions of the Proposed Regulations

We propose to revise § 405.350(c) and § 405.355(b). These proposed revisions would change the timing of the triggering event for the ''without fault'' and ''against equity and good conscience'' presumptions. These revisions are being proposed to reflect the revisions to section 1870 of the Act as specified in by section 638 of ATRA.

Specifically, we propose to change the timeframe at § 405.350(c) so that the rebuttable ''without fault'' presumption for the provider or other person would apply if the Medicare claims based fee-for-service overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid.

Likewise, we propose to amend the timeframe at § 405.355(b) for the presumption ''against equity and good conscience'' for certain types of denials for an individual who is ''without fault'' so that the presumption would apply if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice of payment was sent to the individual.

Additionally, in our review of the current regulation implementing section 1870(c) of the Act, we noted that § 405.355(b) does not clearly reflect the statutory language, which limits the ''against equity and good conscience'' presumption to overpayments associated with denials under section 1862(a)(1) or (a)(9) of the Act. Accordingly, we propose to update and clarify § 405.355(b) so that it clearly reflects the statutory language by adding that the ''against equity and good conscience'' presumption would be applicable for an individual who is ''without fault'' only if the overpayment is related to items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act. In addition, we propose to delete the parenthetical at the end of § 405.355(b) because the regulations referenced no longer exists; those

sections of the regulations were reassigned. (See the October 11, 1989 **FEDERAL REGISTER** (54 FR 41733).) The modifications we propose to § 405.355(b) makes the references in the parenthetical no longer necessary.

G. Physician Compare Web site

1. Background and Statutory Authority

Section 10331 (a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop a Physician Compare Internet 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 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 (*www.medicare.gov/physiciancompare*). In the initial phase, we posted the names of eligible professionals that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that begin 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 intend to continue to address 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 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. This would consist of a 30-day preview period for all measurement performance data that will allow physicians and other eligible professionals to view their data as it will appear on the Web site in advance of publication. Details of the preview process will be communicated on the Physician Compare Initiative page on CMS.gov 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 in selecting quality measures for Physician Compare, which we note we are working to accomplish through a variety of means including rulemaking and various forms of stakeholder outreach. 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 deems 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 Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008).

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. Initial work on this report is currently underway. 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 to make informed decisions about their healthcare, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize Physician Compare to publicly report physician performance results.

2. Public Reporting of Physician Performance Data

Since the initial launch of the Web site, we have continued to build on and improve Physician Compare. In 2013, we launched a full redesign of Physician Compare offering 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 and considerably improving functionality and usability. The primary source of administrative information on Physician Compare is the Provider Enrollment, Chain, and Ownership System (PECOS); as the sole source of verified Medicare professional information, PECOS remains the primary information source. However, with the redesign, we incorporated Medicare claims information to verify the information in PECOS to ensure only the most current and accurate information is included on the site.

With the redesign, users can now search for Medicare physicians and other healthcare professionals by defining a location—a ZIP code, a city/State combination, an exact address, or landmark—and by entering a medical specialty, health care professional or group practice name, a medical condition, body part, or organ system. The site produces a list of suggested specialties, as defined by the 855i Medicare Enrollment Form, users can choose related to their search term or a list of names, as appropriate.

Currently, 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.

As required by 1848(m)(5)(G) of the Act, we are required to post on a CMS Web site the names of eligible professionals who satisfactorily report under the PQRS, as well as those eligible professionals who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program, and Physician Compare contains a link to the list of names. In addition to the list of names, there is a section on each individual's profile page listing the quality programs under which the specific individual satisfactorily reported or was a successful electronic prescriber. The program name is listed and a green check mark clearly indicates participation. These data will be updated annually with the most recent data available.

With the Physician Compare redesign, we have also added a quality programs section to each group practice profile page in order to indicate which group practices are satisfactorily reporting in Group Practice Reporting Option (GPRO) under the PQRS or the eRx Incentive program. We have also included a notation and check mark for individuals that participate in the Medicare EHR Incentive Program, as authorized by section 1848(o)(3)(D) of the Act. These data will be updated with the most recent data available.

As we indicated in the 2013 PFS final rule with comment period (77 FR 69166), we will include a check mark in the quality programs section of the profile page to note those individuals who report the PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative. Finally, a check mark will be added to indicate those individuals who have earned a Maintenance of Certification Additional Incentive starting with data reported for CY 2013. We will update this information annually moving forward.

We are now instituting our plan for a phased approach to public reporting of performance information on Physician Compare. The first phase of our plan was finalized with the 2012 PFS final rule with comment period (77 FR 69166), where we established that PQRS GPRO measures collected through the GPRO Web interface during 2012 would be publicly reported on Physician Compare. These measures will be publicly reported on Physician Compare in CY 2014. We expanded our plan with the 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 include the Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) PQRS GPRO measures, and that we would develop and report composite measures for these measure groups in future years, if technically feasible. For data reported in 2013 under the GPRO, DM and CAD PQRS GPRO measures and composites collected via the GPRO web interface that meet the minimum sample size of 20 patients, and that prove to be statistically valid and reliable, will be publicly reported on Physician Compare in late CY 2014, if technically feasible. As we previously established, 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.

In the Shared Savings Program final rule (76 FR 67948), we noted that because Accountable Care Organization (ACO) providers/suppliers that are eligible professionals are considered to be group practices for purposes of qualifying for a PQRS incentive under the Shared Savings Program, we would publicly report performance on quality measures as we report performance on quality measures for PQRS GPRO group practices. Public reporting of performance on these measures will be presented at the ACO level only.

In the CY 2013 PFS final rule with comment period (77 FR 69167), we also finalized our 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. We anticipate posting these data on Physician Compare as early as 2014.

3. Future Development of Physician Compare

We will continue to phase in an expansion of Physician Compare over the next several years by incorporating quality measures from a variety of sources, as technically feasible. We previously finalized a decision to publicly report on Physician Compare the performance rates on a limited set of Web interface quality measures that group practices submit under the 2012 and 2013 PQRS GPRO Web interface (76 FR 73417 and 77 FR 69166).

For 2014, we propose to expand the quality measures posted on Physician Compare by publicly reporting performance on all measures collected through the GPRO Web interface for groups of all sizes participating in 2014 under the PQRS GPRO and for ACOs participating in the Medicare Shared Savings Program. These data would include measure performance rates for measures reported that met the minimum sample size of 20 patients, and that prove to be statistically valid and reliable. We will provide a 30-day preview period prior to publication of quality data on Physician Compare so that group practices and ACOs can view their data as it will appear on Physician Compare before it is publicly reported. CMS 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.

For 2013 and 2014, we expanded the group reporting option for PQRS GPRO to include a registry reporting option, which we propose to further modify for data reported in 2014 under the PQRS GPRO registry option. Consistent with the requirement under section 10331(a)(2)(A) of the Affordable Care Act to make publicly available information on quality measures submitted by physicians and other eligible professionals under PQRS, we propose to publicly report on Physician Compare performance on certain measures that groups report via registries and EHRs in 2014 for the PQRS GPRO. Specifically, we propose to report, no earlier than 2015, performance on the GPRO registry and EHR measures identified below that can also be reported via the GPRO Web interface in 2014. By proposing to include on Physician Compare performance on these measures reported by participants under the GPRO through registries and EHRs, as well as the GPRO Web interface, we continue to provide beneficiaries with a consistent set of measures over time. For registry reporting, publicly reported measures would include:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Medication Reconciliation.

• Preventive Care and Screening: Influenza Immunization.
• Pneumococcal Vaccination Status for Older Adults.
• Preventive Care and Screening: Breast Cancer Screening.
• Colorectal Cancer Screening.
• Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).
• Adult Weight Screening and Follow-Up.
• Preventive Care and Screening: Screening for Clinical Depression.
• Coronary Artery Disease (CAD): Lipid Control.
• Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
• Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
• Hypertension (HTN): Controlling High Blood Pressure.
• Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
• Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

For EHR reporting, publicly reported measures would include:
• Diabetes: Hemoglobin A1c Poor Control.
• Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
• Preventive Care and Screening: Influenza Immunization.
• Pneumococcal Vaccination Status for Older Adults.
• Preventive Care and Screening: Breast Cancer Screening.
• Colorectal Cancer Screening.
• Adult Weight Screening and Follow-Up.
• Coronary Artery Disease (CAD): Lipid Control.
• Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
• Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
• Hypertension (HTN): Controlling High Blood Pressure.
• Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
• Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

Consistent with the requirement under section 10331(a)(2) of the Affordable Care Act to make comparable information on patient experience of care measures publicly available, we previously finalized a plan to post performance on patient experience survey-based measures from the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) (77 FR 44804) including the following patient experience of care measures for group practices participating in the PQRS GPRO (77 FR 44964):
• CAHPS: Getting Timely Care, Appointments, and Information.
• CAHPS: How Well Your Doctors Communicate.
• CAHPS: Patients' Rating of Doctor.
• CAHPS: Access to Specialists.
• CAHPS: Health Promotion and Education

These measures capture patients' experiences with clinicians and their staff, and patients' perception of care. We finalized a decision to publicly report performance on these measures on Physician Compare in 2014 for data collected for PY 2013 for group practices with 100 or more eligible professionals participating in the PQRS GPRO in 2013 and reporting data through the GPRO Web interface. At least for data reported for 2013, we noted that we would administer and collect patient experience survey data on a sample of the group practices' beneficiaries.

For ACOs participating in the Shared Savings Program, consistent with the PQRS policy of publicly reporting patient experience measures on Physician Compare starting with data collected for CY 2013, we will publicly report patient experience data in addition to the measure data reported through the GPRO Web interface (76 FR 67948). Specifically, the patient experience measures that would be reported for ACOs include the CG-CAHPS measures in the Patient/Caregiver Experience domain finalized in the Shared Savings Program final rule (76 FR 67889):
• CAHPS: Getting Timely Care, Appointments, and Information.
• CAHPS: How Well Your Doctors Communicate.
• CAHPS: Patients' Rating of Doctor.
• CAHPS: Access to Specialists.
• CAHPS: Health Promotion and Education.
• CAHPS: Shared Decision Making
• CAHPS: Health Status/Functional Status

For data reported for 2014, we propose to continue public reporting of these CG-CAHPS data for PQRS GPRO group practices of 100 or more eligible professionals participating in the GPRO via the Web interface and for Shared Savings Program ACOs reporting through the GPRO Web interface or other CMS-approved tool or interface. Consistent with what we finalized for CY 2013 under the PQRS GPRO, we will administer and fund the collection of data for these groups. As we will administer and collect the data for these surveys, we do not anticipate public reporting to impose any notable burden on these groups.

We believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, and under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report under the PQRS, we seek to encourage groups of 25 or more eligible professionals to report CG-CAHPS by proposing to make these measures available for reporting the PQRS and for the Value Based Payment Modifier. We propose to publicly report CY 2014 CG-CAHPS data for any group practice (regardless of size) that voluntarily chooses to report CG-CAHPS; however, CMS will not fund the surveys for these groups. CMS proposes to publically report comparable CG-CAHPS data collected by groups of any size collected via a certified CAHPS vendor.

We are dedicated to publicly reporting accurate, valid, and reliable data on Physician Compare and are aware that each group practice is unique in size and scope. We have closely evaluated the available data collection mechanisms, and are confident that CG-CAHPS is a well-tested collection mechanism with strong support from the healthcare community, and that it provides the best opportunity to collect useful and accurate data for the largest number of group practices. We propose to use only those survey domains that are applicable to group practices or ACOs respectively, and believe that these domains have been well tested, and will therefore provide the best data for the largest number of groups.

In the CY 2013 PFS final rule with comment period (77 FR 44804), we indicated our intention to publicly report performance rates on quality measures included in the 2014 PQRS and for individual eligible professionals consistent with the requirements under section 10331 of the Affordable Care Act to provide information about physicians and other eligible professionals who participate in PQRS. We believe that individual-level measure data is important in helping consumers make informed healthcare decisions and that this information should be posted on the site as soon as technically feasible. Therefore, we propose to publicly report comparable data, as noted below, collected for the CY 2014 PQRS via claims, EHR or registry from individual eligible professionals as early as CY

2015. Specifically, we propose to post individual measures reported by individual eligible professionals in line with those measures reported by groups through the GPRO Web interface. These measures include:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Medication Reconciliation.
- Preventive Care and Screening: Influenza Immunization.
- Pneumococcal Vaccination Status for Older Adults.
- Preventive Care and Screening: Breast Cancer Screening.
- Colorectal Cancer Screening.
- Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).
- Adult Weight Screening and Follow-Up.
- Preventive Care and Screening: Screening for Clinical Depression.
- Coronary Artery Disease (CAD): Lipid Control.
- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
- Hypertension (HTN): Controlling High Blood Pressure.
- Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.
- Falls: Screening for Fall Risk.
- Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control.
- Diabetes Mellitus: High Blood Pressure Control.
- Diabetes Mellitus: Hemoglobin A1c Control (<8%).

Additionally, and in support of the HHS-wide Million Hearts Initiative, we propose to publicly report, no earlier than 2015, performance rates on measures in the PQRS Cardiovascular Prevention measures group (77 FR 44803) at the individual eligible professional level for data collected in 2014 for the PQRS (Table 50).

We seek comment on posting performance on patient experience survey-based measures for individual eligible professionals starting with data collected for CY 2015.

In future years, we will consider expanding public reporting of, and seek comment on, measures that have been developed and collected by approved and vetted specialty societies for individual eligible professionals as well as data collected via the new qualified clinical data registry option being proposed under the PQRS. Additionally, we seek comment on publicly reporting participation by individual eligible healthcare professionals on initiatives such as Choosing Wisely, an initiative of the American Board of Internal Medicine Foundation.

We are committed to making Physician Compare a constructive tool for Medicare beneficiaries, successfully meeting the Affordable Care Act mandate, and providing consumers with information needed to make informed healthcare decisions. We have developed a plan, and begun implementing that plan with a phased approach of adding physician quality data to Physician Compare. We believe this staged approach to public reporting of physician quality information allows consumers access to information that is currently available while we continue to develop the infrastructure necessary to support additional types of data and information on physicians' quality measure performance. We intend to implement subsequent phases of the plan in future rulemaking, as needed.

We invite comments regarding our proposals to: (1) Publicly report performance rates on all quality measures that group practices submit through the GPRO web interface in 2014 under the PQRS GPRO and that ACOs participating in the Medicare Shared Savings Program submit using the GPRO web interface or another CMS-approved tool or interface; (2) publicly report performance on certain quality measures collected under the 2014 PQRS GPRO via registry and EHR reporting mechanisms; (3) publicly report performance on patient experience measures for 2014 both for group practices and ACOs and for group practices of 25 or more professionals who choose to voluntarily report CG-CAHPS data as part of their participation in the PQRS GPRO; (4) publicly report performance on certain measures that are reported by individual eligible professionals reporting through an EHR, registry, or claims during 2014 under the PQRS; and (5) in support of the HHS-wide Million Hearts Initiative, publicly report performance rates for measures included in the Cardiovascular Prevention measures group reported by individual eligible professionals participating in the 2014 PQRS.

We seek comment regarding: (1) Publicly report patient experience survey data under the PQRS for individual eligible professionals, starting with data reported in 2015; and (2) to publicly report participation by individual eligible healthcare professionals on initiatives such as Choosing Wisely, an initiative of the American Board of Internal Medicine Foundation.

For the above proposals, we note that we would only post data on Physician Compare as it is technically feasible and as the data are available.

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

There are several healthcare quality improvement programs that affect physician payments under the Medicare PFS. As we stated previously, we believe that alignment of these quality improvement programs—such as the EHR Incentive Program, Value-based Payment Modifier, and Medicare Shared Savings Program—is critical for programs involving physicians and other healthcare eligible professionals. The proposals that follow facilitate the alignment of programs, reporting systems, and quality measures. We believe that alignment of CMS quality improvement programs will decrease the burden of participation on physicians and allow them to spend more time and resources caring for beneficiaries. Furthermore, as the leaders of care teams and the healthcare systems, physicians and other clinicians serve beneficiaries both as frontline and system-wide change agents to improve quality. We believe that to improve quality, quality measurement and reporting is an important component. It is our intent that the following requirements will further improve alignment of physician-focused quality improvement programs, decrease burden and duplicative reporting for eligible professionals, increase engagement of physicians and other eligible professionals in quality improvement, and ultimately, lead to higher quality care for beneficiaries.

This section contains the requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments and payment adjustments to eligible professionals based on whether or not they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. The regulation governing the PQRS is located at § 414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 PQRS payment adjustment that were

previously established, as well as information on the PQRS, including related laws and established requirements, are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. In addition, the 2011 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/index.html*.

In the CY 2013 PFS final rule with comment period (77 FR 69170), we finalized certain requirements for the 2013 and 2014 PQRS incentives, as well as 2015 and 2016 PQRS payment adjustments. We also finalized certain requirements for future years, such as the reporting periods for the PQRS payment adjustment, as well as requirements for the various PQRS reporting mechanisms. Below, we propose to change some requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment, as well as to make changes to the PQRS measure set. Furthermore, we introduce our proposals for a new PQRS reporting option—satisfactory participation in a qualified clinical data registry. We then seek comment on a general plan for future years for PQRS, so that we may continue to consider stakeholder feedback as we develop policies and proposals for the future.

1. Proposed Changes to § 414.90

As noted previously, the regulation governing the PQRS is located at § 414.90. We are proposing the following changes and technical corrections to § 414.90:

- Under § 414.90(b), we are proposing to modify the definition of administrative claims to eliminate the words ''the proposed'' in the phrase ''on the proposed PQRS quality measures.'' We are proposing to make this technical change because this language was inadvertently included in the final regulation despite the fact that the quality measures that eligible professionals report under the PQRS were finalized in the CY 2013 PFS final rule with comment period (77 FR 69364).
- We propose to modify § 414.90(f) to include the term ''for satisfactory reporting'' after the title ''Use of consensus-based quality measures for satisfactory reporting.'' We are adding the term ''for satisfactory reporting'' so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We propose to modify the paragraph heading of § 414.90(g) to add the term ''satisfactory reporting'', so that the title of the paragraph reads ''Satisfactory reporting requirements for the incentive payments.'' We are proposing to make this change so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We propose to modify the paragraph heading of § 414.90(h) to add the term ''satisfactory reporting'', so that the title of the paragraph reads ''Satisfactory reporting requirements for the incentive payments.'' We are proposing to make this change so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We propose to delete paragraph § 414.90(i)(4), because § 414.90(i)(4) list requirements that are identical to § 414.90(i)(3). Therefore, § 414.90(i)(4) is redundant.

In addition, we are considering further revising the regulation at § 414.90 to list all the specific satisfactory reporting requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment, so that the different reporting requirements are specified in the regulation. We seek public comment on these proposals.

2. Participation as a Group Practice in the Group Practice Reporting Option (GPRO)

a. Proposed Changes to the Self-nomination, or Registration, Requirement for Group Practices To Be Selected to Participate in the GPRO

In the CY 2013 PFS final rule with comment period (77 FR 69172), we finalized requirements for the self-nomination process group practices must follow to participate in the PQRS GPRO. We propose to make two changes to the previously established self-nomination process for group practices. First, we propose to change the deadline for group practices to submit a self-nomination statement, or register, to participate in the PQRS GPRO. We previously established, that in order for a group practice to participate in PQRS under the GPRO, the group practice must submit a self-nomination statement, or register, via the web by October 15 of the year in which the reporting period occurs. Starting with reporting periods occurring in 2014, we propose to change this deadline to September 30 of the year in which the reporting period occurs (that is September 30, 2014 for reporting periods occurring in 2014). We believe that the proposed deadline still gives group practices a reasonable amount of time to make a decision on whether to participate in the PQRS GPRO while allowing CMS more time to pull samples to populate the GPRO web-interface for those group practices that select that particular reporting mechanism. Second, we propose that group practices comprised of 25 or more individual eligible professionals that wish to report the CG CAHPS survey measures (which are discussed later in this section) would be required to elect to report the CG CAHPS survey measures via the web as well. The Web site that a group practice would use to elect to report the CG CAHPS survey measures would be the same Web site used by group practices to register to participate in the PQRS GPRO and used by group practices comprised of 10–99 eligible professionals to elect quality tiering for the Value-based Payment Modifier set forth in section III.M of this proposed rule. We believe that providing a single Web site whereby group practices may make multiple elections (such as submitting the self-nomination statement to register to participate in the PQRS GPRO, be evaluated for the PQRS GPRO using CG CAHPS measures, and also elect quality tiering for the Value-based Payment Modifier) would be desirable for group practices. We seek public comment on the proposed changes to the PQRS GPRO self-nomination process.

3. Proposed Requirements for the PQRS Reporting Mechanisms

The PQRS includes the following reporting mechanisms: Claims, registry, EHR (including direct EHR products and EHR data submission vendor products), administrative claims, and the GPRO web-interface. Section 414.90(g) and (h) govern which reporting mechanisms are available for use by individuals and group practices for the PQRS incentive and payment adjustment. This section contains our proposed changes to these PQRS reporting mechanisms. In addition, this section contains our proposals for two new PQRS reporting mechanisms. We propose a new certified survey vendor reporting mechanism for purposes of reporting CG CAHPS measures described below and a qualified clinical data registry reporting mechanism under the new PQRS ''satisfactory participation'' option.

a. Registry-Based Reporting Mechanism

In the CY 2013 PFS final rule with comment period, we finalized the following requirement for registries to become qualified to participate in PQRS for 2013 and beyond: Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures (77 FR 69180). Since, as we describe in more detail below, we are proposing to increase the number of measures eligible professionals would be required to report for the 2014 PQRS incentive from 3 to 9 measures covering at least 3 of the National Quality Strategy domains, we are proposing to change this registry requirement as follows: 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 domains. We seek public comment on this proposal.

b. Certified Survey Vendors

As discussed later in this section, we are proposing to allow group practices comprised of 25 or more eligible professionals to report CG CAHPS survey measures. The data collected on these CAHPS survey measures would not be transmitted to CMS via the previously established PQRS group practice reporting mechanisms (registry, EHR, or GPRO web interface). Rather, the data must be transmitted through a survey vendor. Therefore, to allow for the survey vendor to transmit survey measures data to CMS, we are proposing to modify § 414.90(b), § 414.90(g)(3), and § 414.90(h)(3) to propose a new reporting mechanism—the certified survey vendor.

In addition, § 414.90(g)(3), and § 414.90(h)(3) currently requires group practices to use only one mechanism to meet the requirements for satisfactory reporting (that is, CMS will not combine data submitted under multiple reporting mechanism to determine if the requirements for satisfactory reporting are met). As discussed further below, we propose that a group practice choosing to report CG CAHPS survey measures would be required to select an additional reporting mechanism to meet the requirements for satisfactory reporting for both the 2014 PQRS incentive and the 2016 PQRS payment adjustment. Therefore, we propose to modify § 414.90(g)(3), and § 414.90(h)(3) to indicate that groups selecting to use the certified survey vendor would be the exception to this requirement.

Specifically, for purposes of PQRS, we are proposing to modify § 414.90(b) to define a certified survey vendor as a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

To obtain CMS certification, we propose that vendors would be required to undergo training, meet CMS standards on how to administer the survey, and submit a quality assurance plan. CMS would provide the identified vendor with an appropriate sample frame of beneficiaries from the group. The vendor would also be required to administer the survey according to established protocols to ensure valid and reliable results. Survey vendors would be supplied with mail and telephone versions of the survey in electronic form, and text for beneficiary pre-notification and cover letters. Surveys can be administered in English, Spanish, Cantonese, Mandarin, Korean, Russian and/or Vietnamese. Vendors would be required to use appropriate quality control, encryption, security and backup procedures to maintain survey response data. The data would then be securely sent back to CMS for scoring and/or validation. To ensure that a vendor possesses the ability to transmit survey measures data for a particular program year, we propose to require survey vendors to undergo this certification process for each year in which the vendor seeks to transmit survey measures data to CMS. We seek public comment on these proposals.

4. Proposed Changes to the Criteria for the Satisfactory Reporting for Individual Eligible Professionals for the 2014 PQRS Incentive—Individual Quality Measures Submitted via Claims and Registries and Measures Groups Submitted via Claims

Individual eligible professionals may currently report PQRS quality measures data to meet the criteria for satisfactory reporting for the 2014 PQRS incentive via the claims, registry, and EHR-based reporting mechanisms. This section contains our proposed changes to the criteria for satisfactory reporting of individual quality measures via claims and registries by individual eligible professionals for the 2014 PQRS incentive. Please note that we are not proposing to modify the criteria for satisfactory reporting of individual quality measures via EHR that were established in the CY 2013 PFS final rule with comment period (see Table 91, 77 FR 69194).

a. Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Claims for Individual Eligible Professionals for the 2014 PQRS Incentive

For 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. In the CY 2013 PFS final rule with comment period (*see* Table 91, 77 FR 69194), to maintain the reporting criterion with which individual eligible professionals are familiar, we finalized the same satisfactory reporting criterion for the submission of individual quality measures via claims that we finalized in previous years: For the 12-month reporting period for the 2014 PQRS incentive, report at least 3 measures, OR, if less than 3 measures apply to the eligible professional, report 1–2 measures, 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. For an eligible professional who reports fewer than 3 measures via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures (77 FR 69188).

For the reasons described below and based on our authority to revise the criteria for satisfactory reporting for the 2014 PQRS incentive under section 1848(m)(3)(d) of the Act, we propose to change the criterion for the satisfactory reporting of individual, claims-based measures by individual eligible professionals for the 2014 PQRS incentive as follows: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy 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 via the claims-based reporting mechanism, 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.

We note that this proposal would increase the number of measures an eligible professional is required to report via the claims-based reporting mechanism from 3 measures to 9. We understand that this is a significant increase in the number of measures an eligible professionals is required to report. However, we believe that the need to collect enough quality measures data to better capture the picture of the care being furnished to a beneficiary, especially when this data may be used to evaluate an eligible professional's quality performance under the Value-based Payment Modifier, justifies the increase in measures.

We seek public comment on the proposed change to the criterion for the satisfactory reporting of individual quality measures via claims for individual eligible professionals for the 2014 PQRS incentive.

b. Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Registry for Individual Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period, to maintain reporting criterion with which individual eligible professionals are familiar, we finalized the same satisfactory reporting criterion for individual eligible professionals to report individual quality measures via registry that we finalized in previous years: For the 12-month reporting period for the 2014 PQRS incentive, report at least 3 measures and report each measure for at least 80 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 (77 FR 69189). We propose to change this reporting criterion for individual eligible professionals reporting via registry for the 2014 PQRS incentive to the following: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy 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. Measures with a 0 percent performance rate would not be counted.

We note that this proposal would increase the number of measures an eligible professional is required to report via the registry-based reporting mechanism from 3 measures to 9 covering at least 3 of the National Quality Strategy domains. We understand that this is a significant increase in the number of measures an eligible professional is required to report. However, similar to the reasons we provided for proposing to increase the measure threshold from 3 measures to 9 for the claims-based reporting mechanism, we believe that the need to collect enough quality measures data to better capture the picture of the care being furnished to a beneficiary, especially when this data may be used to evaluate an eligible professional's quality performance under the Value-based Payment Modifier, justifies the change. We believe that collecting data on 9 measures applicable to an eligible professional's practice as opposed to 3 measures would provide us with a better picture of the overall quality of care furnished by that eligible professional for purposes of having PQRS reporting being used to assess quality performance under the Value-based Payment Modifier. We also note that, as PQRS has used this same 3-measure criterion since the registry-based reporting mechanism was introduced in 2010, it would be conceivable that we would eventually propose to increase the number of measures an eligible professional is required to report. Our proposal to increase the number of measures reported via claims and registry would align with our established reporting option for the EHR-based reporting mechanism or the 2014 PQRS incentive, which requires the reporting of 9 measures covering 3 of the National Quality Strategy domains (77 FR 69189).

In addition, we note that this proposal would also decrease the number of patients for which an eligible professional must report for each measure from 80 percent to 50 percent of an eligible professional's applicable patients. We are proposing to drop the percentage threshold from 80 to 50 percent primarily to align our percentage thresholds for registry reporting with the percentage threshold established for reporting via the claims-based reporting mechanism. We believe it is appropriate to drop the percentage threshold to 50, particularly since we are proposing to also increase the number of measures an eligible professional is required to report via the registry-based reporting mechanism from 3 to 9 measures covering at least 3 of the National Quality Strategy domains. The criteria for satisfactory reporting that we are proposing for the 2014 PQRS incentive payment are described in Table 24.

We seek public comment on the proposed changes to the criterion for the satisfactory reporting of individual quality measures via registry for individual eligible professionals for the 2014 PQRS incentive.

c. Proposed Changes to the Criterion for Satisfactory Reporting of Measures Groups via Claims for Individual Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period, we finalized the following criteria for satisfactory reporting for individual eligible professionals to report measures groups via claims: Report at least 1 measures group and report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a zero percent performance rate will not be counted (77 FR 69192). Since finalizing this criterion, we have recently published and analyzed the 2011 PQRS and eRx Experience Report, which provides a summary of PQRS reporting trends from 2007 through 2011, to determine where we may work to further streamline the reporting options available under the PQRS. The PQRS and eRx Experience Report stated that the number of eligible professionals who participated via claims-based measures groups reporting mechanism grew more than three-fold between 2008 and 2011. However, according to Appendix 8 of the PQRS and eRx Experience Report titled ''Eligible Professionals who Participated by Reporting Measures Groups through the Claims Reporting Mechanism for the Physician Quality Reporting System, by Specialty (2008 to 2011),'' only 4,472 eligible professionals used this reporting option. Meanwhile, the Experience Report further shows that the option to report measures groups via registry has grown at an even faster rate with 12,894 participants in 2011. Therefore, in an effort to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used, we are proposing to remove this satisfactory reporting criterion for the 2014 PQRS incentive. Please note that, since we are proposing to remove this reporting criterion, the only manner in which an eligible professional would be able to report a PQRS measures group would be via registry. We seek public comment on this proposal.

5. Proposed Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Individual Eligible Professionals Using the Claims and Registry Reporting Mechanisms

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 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.

In the CY 2013 PFS final rule, we finalized seven different criteria for the satisfactory reporting by individual eligible professionals of data in PQRS quality measures for the 2016 PQRS payment adjustment (*see* 77 FR 69200–69204 and Table 91 at 77 FR 69194). Although we are retaining five of the final criteria for satisfactory reporting by individual eligible professionals of data on PQRS quality measures for the 2016 PQRS payment adjustment, we propose to eliminate two criteria, revise another, and include two additional criteria (based on two of the existing criteria). Specifically, we propose to remove the following criterion we previously finalized for the CY 2016 payment adjustment for individual eligible professionals reporting measures groups through claims (77 FR 69200 and Table 91, 77 FR 69164): Report at least 1 measures group and report each measures group for at least 20 Medicare Part B FFS patients (Measures groups containing a measure with a zero percent performance rate will not be counted). Our proposal to remove this criterion would correspond to the same proposal we are making, as discussed above, for the 2014 PQRS incentive for individual eligible professionals. As we indicated, we believe it is important to streamline the program and eliminate criteria for reporting options that are not widely used.

We also propose to remove the following criterion we previously finalized for the 2016 payment adjustment for individual eligible professionals reporting individual measures through a qualified registry (77 FR 69200 and Table 91, 77 FR 69164): Report at least 3 measures, and report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measures applies (Measures with a zero percent performance rate will not be counted). Finally, to maintain some consistency and to otherwise align with the criteria we are proposing for the 2014 PQRS incentive for individual eligible professionals, we are proposing two other criteria for satisfactory reporting by individual eligible professionals for the 2016 PQRS payment adjustment using the claims and registry reporting mechanisms. Specifically, we propose the following criterion for reporting individual measures via claims by individual eligible professionals for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy 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. Similarly, for the same reasons we discussed previously, we propose the following criterion for reporting individual measures via qualified registry by individual eligible professionals for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50% 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.

Please note that in the CY 2013 PFS final rule, we finalized the same criteria for satisfactorily reporting data on quality measures for covered professional services for the 2016 PQRS payment adjustment as those for the 2014 PQRS incentive for individual eligible professionals (77 FR 69200). However, if the proposals we are making in this proposed rule were finalized, there would be some differences between the criteria for satisfactory reporting for the 2016 PQRS payment adjustment and the 2014 PQRS incentive. In particular, there would be one more criterion for satisfactory reporting for the 2016 payment adjustment than for the 2014 PQRS incentive with respect to claims-based reporting, but the other criteria would otherwise align. Although we considered, as an alternative, to propose to remove the criterion we previously finalized for the 2016 payment adjustment for individual eligible professionals reporting individual measures through claims, we believe it is still important to offer as many options as possible for the 2016 PQRS payment adjustment, particularly since the penalty phase is relatively new under the PQRS. We also note that it would remain true that if an individual eligible professional were to meet any of the criteria for satisfactory reporting for the 2014 PQRS incentive, the individual eligible professional would meet the requirements for satisfactory reporting for the 2016 PQRS payment adjustment (note, however, that the reverse would not necessarily be true since there would be one additional criterion for satisfactory reporting for the 2016 PQRS payment adjustment that would not apply to the 2014 PQRS incentive).

The criteria for satisfactory reporting that we are proposing for the 2016 PQRS payment adjustment are described in Table 25. We believe such alignment still serves to reduce reporting burden, and as we have noted previously, we believe that proposing similar criteria for satisfactory reporting by individual eligible professionals for the 2014 PQRS incentive and 2016 PQRS payment adjustment is appropriate because the reporting period for the 2014 PQRS incentive and 2016 PQRS payment adjustment coincide. As we continue to implement the PQRS payment adjustment and fully implement the value-based payment modifier in 2017, it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive.

We seek public comment on our proposed satisfactory reporting criteria for individual eligible professionals for the 2016 PQRS payment adjustment, including the alternative proposal considered for individual eligible professionals reporting individual measures through the claims-based reporting mechanism.

6. Proposals Related to Satisfactory Participation in a Qualified Clinical Data Registry by Individual Eligible Professionals

Section 601(b) of the American Taxpayer Relief Act of 2012 amends section 1848(m)(3) of the Act, by redesignating subparagraph (D) as subparagraph (F) and adding new subparagraph (D), to provide for a new standard for individual eligible professionals to satisfy the PQRS beginning in 2014, based on satisfactory participation in a qualified clinical data registry. Below, we set forth our proposals for implementing this provision, including the proposed requirements for qualified clinical data registries and our proposals for individual eligible professionals to

satisfactorily participate in a qualified clinical data registry with respect to the 2014 PQRS incentive and 2016 PQRS payment adjustment.

On February 7, 2013, CMS published a Request for Information titled ''Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs'' (78 FR 9057). The Request for Information included a solicitation for comments about section 601(b) of the American Taxpayer Relief Act of 2012. CMS received over 100 comments on this Request for Information, and much of the information provided in these comments were used to shape the proposals set forth in this section.

a. Proposed Definition of a Qualified Clinical Data Registry

Under section 1848(m)(3)(D) of the Act, as amended and added by section 601(b)(1) of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted January 2, 2013), for 2014 and subsequent years, the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures if, in lieu of reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry for the year. Section 1848(m)(3)(E) of the Act, as added by section 601(b)(1) of the American Taxpayer Relief Act of 2012, authorizes the Secretary to define a qualified clinical data registry under the PQRS. Specifically, the Secretary is required to establish requirements for an entity to be considered a qualified clinical data registry (including that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out the provision). And in establishing such requirements, the Secretary must take certain factors into consideration.

Generally, registries are entities that collect data related to patients with a specific diagnosis, condition, or procedure. In fact, the collection and submission of PQRS quality measures data on behalf of eligible professionals are the functions a traditional ''qualified registry'' currently performs under the PQRS for purposes of eligible professionals satisfactorily reporting. The majority of commenters in response to the February 7, 2013 Request for Information stated that these qualified clinical data registries should serve additional roles aimed at quality improvement other than collecting and transmitting quality data to CMS. The commenters saw qualified clinical data registries as entities that should be at the forefront of quality improvement. We agree with the commenters. Therefore, we believe that a ''qualified clinical data registry'' specified under section 1848(m)(3)(E) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, should serve additional roles that foster quality improvement in addition to the collection and submission of quality measures data.

Section 1848(m)(3)(E)(ii) of the Act, as added by section 601(b)(1) of the American Taxpayer Relief Act of 2012, provides that, when determining whether an entity should be considered a qualified clinical data registry, the Secretary shall take into consideration whether the entity:

- Has in place mechanisms for the transparency of data elements and specifications, risk models, and measures;
- Requires the submission of data from participants with respect to multiple payers;
- Provides timely performance reports to participants at the individual participant level; and
- Supports quality improvement initiatives for participants.

As an example of quality improvement initiatives by a clinical data registry, we note that the Society of Thoracic Surgeons established the STS National Database in 1989 for the purpose of quality assessment, improvement, and patient safety among cardiothoracic surgeons. The STS National Database, which serves a traditional qualified registry under the PQRS, provides:

- A standardized, nationally benchmarked tool for assessing the care of patients undergoing cardiothoracic operations;
- The opportunity to participate in national quality improvement efforts for cardiothoracic surgery that have an impact at the local, regional, and national levels;
- A mechanism to target specific areas for clinical practice improvement;
- The ability to investigate regional and national practice patterns in cardiothoracic surgery; and
- The ability to conduct clinical and comparative effectiveness research using national aggregate data set.

While we do not believe that it is necessary for a qualified clinical data registry to possess all of these characteristics for purposes of the PQRS, we do believe that it is important for a qualified clinical data registry to possess the following characteristics:

- Benchmarking capacity for assessing the care furnished to patients by the eligible professionals participating in the qualified clinical data registry. We believe it is important that a qualified clinical data registry possess benchmarking capacity in order to be able to compare the quality of care furnished by eligible professionals so that eligible professionals using the qualified clinical data registry are aware of how the care they furnished is rated as compared to other professionals. Eligible professionals would be able to use this information to adjust the care they provide, if appropriate. While having the capacity to benchmark performance nationally is preferable, we believe that a qualified clinical data registry should, at a minimum, possess the capacity to benchmark performance across the eligible professionals using the qualified clinical data registry.
- The ability to provide timely and frequent feedback to its eligible professionals. We believe it is important for eligible professionals using a clinical data registry to receive frequent and timely feedback on the quality measures data they report through the qualified clinical data registry. A traditional PQRS registry is required to provide at least 2 feedback reports to eligible professionals using the registry. Since we believe that qualified clinical data registries should possess a more robust system, we believe that qualified clinical data registries should provide timely feedback at least quarterly so eligible professionals could view their reporting at least 4 times during the yearly reporting period.

Therefore, based on CMS' authority to define a qualified clinical data registry under section 1848(m)(3)(E) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, and accounting for the considerations addressed in section 1848(m)(3)(E)(ii) of the Act and for the reasons stated above, we propose to modify § 414.90(b) to add a proposed definition for a qualified clinical data registry. Specifically, we propose to define a ''qualified clinical data registry'' for purposes of the PQRS as a CMS-approved entity (such as a registry, certification board, collaborative, etc.) that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patients.

First, we propose that a qualified clinical data registry must be able to submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible

professionals have satisfactorily participated in PQRS. We propose that a qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures. Second, with regard to the consideration under section 1848(m)(3)(E)(ii)(II) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012 that requires the submission of data from participants with respect to multiple payers, we propose that the data a qualified clinical data registry submitted to CMS for purposes of demonstrating satisfactory participation be quality measures data on multiple payers, not just Medicare patients.

Third, with regard to the consideration under section 1848(m)(3)(E)(ii)(III) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, that a qualified clinical data registry provide timely performance reports to participants at the individual participant level, we propose that a qualified clinical data registry must provide timely feedback at least quarterly on the measures for which the qualified clinical data registry would report on the individual eligible professional's behalf for purposes of the eligible professional meeting the criteria for satisfactory participation under PQRS.

Fourth, to address section 1848(m)(3)(E)(ii)(IV) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, regarding whether a qualified clinical data registry supports quality improvement initiatives for its participants, we propose to require that a qualified clinical data registry possess a method to benchmark the quality of care measures an eligible professional provides with that of other eligible professionals performing the same or similar functions. Benchmarking would require that a qualified clinical data registry provide metrics to compare the quality of care its participating eligible professional provides. For example, the National Committee for Quality Assurance (NCQA) provides national and regional benchmarks for certain measures. Adopting benchmarks such as those provided by NCQA could serve to satisfy this requirement.

Please note that it is possible for an entity to serve as a traditional, qualified registry and/or a qualified clinical data registry under the PQRS.

b. Proposed Requirements for a Qualified Clinical Data Registry

As we noted above, we are required, under section 1848(m)(3)(E)(i) of the Act, to establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out this subsection. Section 1848(m)(3)(E)(iv) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, requires CMS to consult with interested parties in carrying out this provision.

Pursuant to this authority to establish the requirements for an entity to be considered a qualified clinical data registry, we are proposing the following requirements that an entity must meet to serve as a qualified clinical data registry under the PQRS:

First, we are proposing the following requirements to ensure that the entity seeking to become a qualified clinical data registry is well-established:

- Be in existence as of January 1 the year prior to the year for which the entity seeks to become a qualified clinical data registry (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014). This proposed requirement is also required of a traditional qualified registry. We believe it is important for an entity to test out its business practices to ensure that the practices it adopts truly foster the improvement of quality care prior to seeking to become a qualified clinical data registry. We believe that entities that have been in existence for less than one year prior to the year for which the entity seeks to become a qualified clinical data registry have not had an adequate opportunity to do so.
- Have at least 100 clinical data registry participants by January 1 the year prior to the year for which the entity seeks to submit clinical quality measures data (for example, January 1, 2013, to be eligible to participate under the program with regard to data collected in 2014). Please note that not all participants would be required to participate in PQRS. We are proposing this requirement to ensure that the entity seeking to become a qualified clinical data registry is sufficient in size and technical capability. As we believe that a qualified clinical data registry should be more robust in technical capabilities than a traditional PQRS-qualified registry, we believe that a qualified clinical data registry should be sufficiently larger in size than a traditional PQRS-qualified registry. Therefore, whereas we only required a traditional PQRS-qualified registry to have at least 25 registry participants, we believe it is appropriate that we require that a qualified clinical data registry have at least 100 participants.
- Not be owned or managed by an individual, locally-owned, single-specialty group (for example, single-specialty practices with only 1 practice location or solo practitioner practices would be precluded from becoming a qualified clinical data registry).

In addition, for transparency purposes, we propose that a qualified clinical data registry must:

- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the qualified clinical data registry's receipt of patient-specific data from the eligible professionals as well as the qualified clinical data registry's public disclosure of quality measure results.
- Describe to CMS the cost for eligible professionals that the qualified clinical data registry charges to submit data to CMS.

We are also proposing to require qualified clinical data registries to meet the following requirements pertaining to the transmission of quality measures data to CMS:

- To ensure that the qualified clinical data registry is compliant with applicable privacy and security laws and regulations, the entity must describe its plan to maintain Data Privacy and Security for data transmission, storage and reporting.
- Comply with a CMS-specified secure method for quality data submission.
- Provide information on each measure to be reported by an eligible professional, including a summary of supporting evidence/rationale, title, numerator, denominator, exclusions/exceptions, data elements and value sets in addition to measure level reporting rates, patient-level demographic data and/or the data elements needed to calculate the reporting rates by TIN/NPI.
- Submit an acceptable ''validation strategy'' to CMS by March 31 of the reporting year the entity seeks qualification (for example, if an entity wishes to become qualified for participation with regard to data collected in 2014, this validation strategy would be required to be submitted to CMS by March 31, 2014). A validation strategy would detail how the qualified clinical data registry will determine whether eligible professionals succeed in reporting clinical quality measures. Acceptable

validation strategies often include such provisions as the entity being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. For a template for data validation and integrity, please also see the requirements for certification of an EHR product by the Office of the National Coordinator for Health Information Technology (ONC) that are explained at *http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method*.

- Perform the validation outlined in the strategy and send evidence of successful results to CMS by June 30 of the year following the reporting period (for example, June 30, 2015, for data collected in the reporting periods occurring in 2014).
- Obtain and keep on file for at least 7 years signed documentation that each holder of an NPI whose data are submitted to the qualified clinical data registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on beneficiaries to CMS for the purpose of PQRS participation. This documentation would be required to be obtained at the time the eligible professional signs up with the qualified clinical data registry to submit quality measures data to the qualified clinical data registry and would be required to meet any applicable laws, regulations, and contractual business associate agreements.
- Upon request and for oversight purposes, provide CMS access to the qualified clinical data registry's database to review the beneficiary data on which the qualified clinical data registry-based submissions are based or provide to CMS a copy of the actual data.
- Prior to CMS posting the list of qualified clinical data registries for a particular year, verify the information contained on the list (includes names, contact information, measures, cost, etc.) and agree to furnish/support all of the services listed on the list.
- Make available to CMS samples of patient level data to audit the entity for purposes of validating the data submitted to CMS by the qualified clinical data registry, if determined to be necessary.
- The entity must provide information on how the entity collects quality measurement data, if requested.
- By March 31 of the year in which the entity seeks to participate in PQRS as a qualified clinical data registry, the entity must publically post (on the entity's Web site or other publication available to the public) a detailed description (rationale, numerator, denominator, exclusions/exceptions, data elements) of the quality measures it collects to ensure transparency of information to the public.
- The entity must report, on behalf of its individual eligible professional participants, a minimum of 9 measures that cross 3 National Quality Strategy domains.
- The entity, on behalf of its individual eligible professional participants, must report on at least one outcomes-based measure (defined in this section below).
- The entity, on behalf of its individual eligible professional participants, must report on a set of measures from one or more of the following categories: CG-CAHPS; NQF endorsed measures (information of which is available at *http://www.qualityforum.org/Home.aspx*); current PQRS measures; measures used by boards or specialty societies; and measures used in regional quality collaboratives.
- The entity must demonstrate that it has a plan to publicly report their 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. As an alternative, we considered requiring that the entity must benchmark within its own registry for purposes of determining relative quality performance where appropriate.
- The entity must demonstrate that it has a plan to risk adjust the quality measures data for which it collects and intends to transmit to CMS, where appropriate. Risk adjustment has been described as a corrective tool used to level the playing field regarding the reporting of patient outcomes, adjusting for the differences in risk among specific patients (*http://www.sts.org/patient-information/what-risk-adjustment*). Risk adjustment also makes it possible to compare performance fairly. For example, if an 86 year old female with diabetes undergoes bypass surgery, there is less chance for a good outcome when compared with a healthy 40 year old male undergoing the same procedure. To take factors into account which influence outcomes, for example, advanced age, emergency operation, previous heart surgery, a risk adjusted model is used to report surgery results.

Should CMS find, pursuant to an audit, that a qualified clinical data registry has submitted inaccurate data, CMS proposes to disqualify the qualified clinical data registry, meaning the entity will not be allowed to submit quality measures data on behalf of its eligible professionals for purposes of meeting the criteria for satisfactory participation for the following year. Should an entity be disqualified, the entity must again become a qualified clinical data registry before it may submit quality measures data on behalf of its eligible professionals for purposes of the individual eligible professional participants meeting the criteria for satisfactory participation under the PQRS. Additionally, we propose that the inaccurate data collected would be discounted for purposes of an individual eligible professional meeting the criteria for satisfactory participation in a qualified clinical data registry. We seek comments on these proposals.

As we noted, section 1848(m)(3)(E)(i) of the Act, as added by section 601(b) of the American Tax Relief Act of 2012, requires us to establish requirements for an entity to be considered a qualified clinical data registry, including that the entity provide us with such information, at such times, and in such manner, as we determine necessary to carry out the provision. Given the broad discretion afforded under the statute, we propose that qualified clinical data registries provide CMS with the quality measures data it collects from its eligible professional participants. We believe it is important that a qualified clinical data registry provide such data for a number of reasons. As we discuss in greater detail below, we believe such information is necessary for purposes of determining whether individual eligible professionals have satisfactorily participated in a clinical qualified data registry under the PQRS. In addition, as discussed in section K, we are proposing to use the quality measures data reported under the PQRS to assess eligible professionals with regard to applying the Value-based Payment Modifier in an upward, downward, and neutral adjustment to an eligible professional's Medicare Part B PFS charges. Therefore, we propose to require that qualified clinical data registries submit quality measures data to CMS. Specifically, to further ensure that the quality measures data elements are reported to CMS in standardized manner, we propose to require that qualified clinical data registries be able to collect all needed data elements and transmit the data on quality measures to CMS, upon request, in one of two formats, either via a CMS-approved XML format or via the Quality Reporting

Document Architecture (QRDA) category III format. The CMS-approved XML format is consistent with how traditional qualified registries under the PQRS transmit data on quality measures to CMS. While our preference would be to receive data on quality measures via the QRDA category III format only since the QRDA category III format is one of the formats we require for an EP's EHR or an EHR data submission vendor to submit quality measures data (see 77 FR 69183), we understand that the quality measures data collected by qualified clinical data registries vary and that these qualified clinical data registries may not be equipped to submit quality measures data to CMS using the QRDA category III format. In future years, it is our intention to require all qualified clinical data registries to provide quality measures data via the QRDA category III format.

To ensure that the data provided by the qualified clinical data registry is correct, we propose to require that qualified clinical data registries provide CMS a signed, written attestation statement via email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

We propose that, regardless of whether the eligible professional uses the XML or QRDA III format to report quality measures data to CMS, the qualified clinical data registry would be required to submit this data no later than the last Friday occurring 2 months after the end of the respective reporting period (that is, February 27, 2015 for reporting periods occurring in 2014). We also propose that, if a qualified clinical data registry is submitting quality measures data on behalf of individual eligible professionals that are part of the same group practice (but not participating in the PQRS GPRO), the qualified clinical data registry would have the option to report the quality measures data to CMS in a batch containing data for each of the individual eligible professionals within the group practice, rather than submitting individual files for each eligible professional.

In conjunction with our proposal to require that qualified clinical data registries be able to provide data on quality measures in a CMS-approved XML format, we propose to require that qualified clinical data registries report back to participants on the completeness, integrity, and accuracy of its participants' data. We believe that it would be beneficial to the participants to receive feedback on the data transmission process so that the participants are aware of any inaccuracies transmitted to CMS.

Alternatively, with respect to the information CMS would require a qualified clinical data registry to furnish to CMS to determine that the eligible professionals have met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment, in lieu of accepting quality measures data for reporting periods occurring in 2014 only, we considered proposing that a qualified clinical data registry provide CMS with a list of the eligible professionals (containing the respective eligible professionals' TIN/NPI information) who participated in and reported quality data to the qualified clinical data registry in order to determine which individual eligible professionals met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We considered this alternative because we do not have experience collecting data from qualified clinical data registries, we are unfamiliar with the type of quality data qualified clinical data registries collect, and we are still building out our data infrastructure.

We seek public comment on these proposals.

c. Proposed Process for Being Designated as a Qualified Clinical Data Registry

Section 1848(m)(3)(E)(v) of the Act, as added by section 601(b) of the American Taxpayer Relief Act of 2012, requires the Secretary to establish a process to determine whether or not an entity meets the requirements established under section 1848(m)(3)(E)(i) of the Act. Such process may involve one or both of the following: (I) A determination by the Secretary; (II) A designation by the Secretary of one or more independent organizations to make such determination. This section sets forth our proposals for our process to determine whether or not an entity should be designated as a qualified clinical data registry.

Consistent with what we require of traditional qualified registries under the PQRS, we propose that an entity must submit a self-nomination statement that indicates its intent to participate in PQRS as a qualified clinical data registry. We believe this self-nomination statement is necessary for CMS to anticipate how many clinical data registries would participate for a certain year as well as provide information to eligible professionals about potential participating clinical data registries. We propose that the self-nomination statement contain the following information:

- The name of the entity seeking to become a qualified clinical data registry.
- The entity's contact information, including phone number, email, and mailing address.
- A point of contact, including the contact's email address and phone number, for which to notify the entity of the status of its request to be considered a qualified clinical data registry.
- The measure title, description, and specifications for each measure the qualified clinical data registry would require its eligible professionals to report for purposes of participating in PQRS. In addition, the qualified clinical data registry must describe the rationale and evidence basis to support each measure it would require its eligible professionals to report.
- The reporting period start date the entity will cover as a clinical data registry.

Since we believe that accepting these statements via email would be the most efficient method for collecting and processing self-nomination statements, we propose to accept self-nomination statements via email only. However, in the event that it is not technically feasible to collect this self-nomination statement via email, we propose that entities seeking to become qualified clinical data registries submit its self-nomination statement via a mailed letter to CMS. The self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244–1850.

To ensure that CMS is able to process these self-nomination statements as early as possible, we propose that these self-nomination statements must be received by CMS by 5:00 p.m. Eastern Standard Time on January 31 of the year in which the clinical data registry seeks to be qualified (that is, January 31, 2014 for purposes of becoming a qualified clinical data registry for the reporting periods for the 2014 PQRS incentive and 2016 PQRS payment adjustment). We understand that this is an early proposed deadline, particularly since this is a new reporting mechanism. However, it is necessary for us to propose a deadline of January 31 to ensure that we have sufficient time to analyze the self-nomination statements we receive, ensure that the entity meets the basic requirements for being designated as a qualified clinical data

registry, including whether or not the quality measures the entity intends to report on behalf of eligible professionals meet the requirements set forth in section I.11 of this proposed rule, and allow for sufficient time for eligible professionals to view a list of entities that are qualified as clinical data registries for the year prior to the end of the applicable reporting period for satisfactory participation in a qualified clinical data registry. We anticipate posting a list of the entities that are designated by CMS as qualified clinical data registries in the Fall of the same year.

Since participation in a qualified clinical data registry is a new option for individual eligible professionals, we anticipate making changes to the requirements for becoming a qualified clinical data registry in future rulemaking as we gain more experience with this option. Since we believe it is important that the entity keep up with these changes, at this time, we propose that entities seeking to serve as qualified clinical data registries must self-nominate for each year that the entity seeks to participate. In the future, we anticipate moving towards a 2-year self-nomination process as the requirements for qualified clinical data registries become firmly established; however, at this time, we are proposing self-nomination for any year in which a qualified clinical data registry intends to participate under the PQRS.

We seek public comment on these proposals.

d. Proposed Reporting Period for the Satisfactory Participation by Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2014 PQRS Incentive

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the America Taxpayer Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with the reporting period applicable to individual eligible professionals who report quality measures data under section 1848(m)(3)(A), we propose to modify § 414.90(c)(5) to specify a 12-month, calendar year (CY) reporting period from January 1, 2014 through December 31, 2014 for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for purposes of the 2014 PQRS incentive. We are proposing a 12-month reporting period. Based on our experience with the 12 and 6-month reporting periods for the PQRS incentives, we believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on shorter reporting periods. In addition, we believe a 12-month reporting period is appropriate given that the full calendar year would be utilized with regard to the participation by the individual eligible professional in the qualified clinical data registry. We invite public comment on the proposed 12-month, CY 2014 reporting period for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive.

e. Proposed Criteria for Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2014 PQRS Incentive

For 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the America Taxpayer Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(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 qualified clinical data registry 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 earn a PQRS incentive or avoid the PQRS payment adjustment. Therefore, we propose to modify § 414.90 to add paragraph (c)(5) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures if individual eligible professionals satisfactorily participate in a qualified clinical data registry for purposes of the PQRS incentive. This section also contains the criterion we are proposing for individual eligible professionals to meet to satisfactorily participate in a qualified clinical data registry for purposes of the 2014 PQRS incentive.

We understand that qualified clinical data registries may have different ways to measure success in quality reporting among its registry participants. However, for purposes of the 2014 PQRS incentive, CMS must establish a standard for satisfactory participation in a qualified clinical data registry. Therefore, we propose that, to meet the criteria for satisfactory participation for the 2014 PQRS incentive, an individual eligible professional would be required to: For the 12-month 2014 reporting period, report at least 9 measures available for reporting under the qualified clinical data registry covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the eligible professional's applicable patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure. We further propose that a qualified clinical data registry may submit data on more than 9 quality measures on behalf on an eligible professional. However, we propose that a qualified clinical data registry may not submit data on more than 20 measures on behalf of an eligible professional. We propose to place a limit on the number of measures that a qualified clinical data registry may submit on behalf of an eligible professional at this time because we have no experience with qualified clinical data registries and the types of data on quality measures that they collect.

We note that this proposed criterion for satisfactory participation is consistent with proposed requirements set forth (for example, the reporting period as well as the number of individual measures, domains, and applicable patients proposed to be reported) for meeting the criteria for the satisfactory reporting of individual PQRS quality measures using the traditional claims, registry, and EHR-based reporting mechanisms for the 2014 PQRS incentive (for example, the reporting period as well as the number of individual measures, domains, and applicable patients proposed to be reported). We believe it is important to propose a similar quality data reporting criterion for individual eligible professionals to satisfactorily participate in a qualified clinical data registry as for satisfactory reporting for the 2014 PQRS incentive so that this proposed satisfactory participation option to

satisfy the PQRS is not disproportionately more advantageous or less burdensome than the other proposed criteria for satisfactory reporting for the 2014 PQRS incentive. However, this proposed criterion for satisfactory participation departs from the proposed criteria for satisfactory reporting for the 2014 PQRS incentive in a number of ways. First, an eligible professional using a qualified clinical data registry is required to report on at least 1 outcome measure. Second, whereas the proposed criteria for satisfactory reporting on individual PQRS quality measures require the reporting of at least 1 Medicare Part B FFS patient, this proposed criterion for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive would not require reporting on Medicare patients. Please note that because we are also proposing more stringent requirements for an entity to become a qualified clinical data registry than a traditional qualified registry, such as requiring benchmarking capacity, we believe that individual eligible professionals who participate in a qualified clinical data registry would be doing more than just reporting quality data to the qualified data registry for PQRS purposes. Over time, as we gain more experience with the capabilities of qualified clinical data registries, we anticipate that the criteria for satisfactory participation will further depart from the criteria for satisfactory reporting under PQRS and incorporate other quality improvement functions that may be provided by a qualified clinical data registry to its participants as this option evolves.

We seek public comment on the proposed criterion for the satisfactory participation by individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive.

f. Proposed Reporting Period for the Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2016 PQRS Payment Adjustment

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the American Tax Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with how individual eligible professionals report quality measures data to a qualified clinical data registry, we propose to modify § 414.90(e)(2) to specify a 12-month, calendar year (CY) reporting period from January 1, 2014 through December 31, 2014, for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for purposes of the 2016 PQRS payment adjustment. We are proposing a 12-month reporting period because, based on our experience with the 12 and 6-month reporting periods for the PQRS incentives, we believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on shorter reporting period. We also believe that a 12-month reporting period is appropriate given that the full calendar year would be utilized with regard to the participation by the individual eligible professional in the qualified clinical data registry.

We are proposing a 12-month reporting period occurring 2 years prior to the application of the 2016 PQRS payment adjustment for individual eligible professionals to allow time to perform all reporting analyses, and make determinations about whether the individual eligible professional satisfactorily participated in a qualified clinical data registry, prior to applying payment adjustments on eligible professionals' Medicare Part B PFS claims in 2016. However, in future years, we may propose alternative reporting periods that could occur closer in time to the application of the PQRS payment adjustment. We invite public comment on the proposed 12-month, CY 2014 reporting period (that is, January 1, 2014–December 31, 2014) for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment.

g. Proposed Criteria for the Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2016 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 redesignated and added by section 601(b) of the American Tax Relief Act of 2012, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(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 qualified clinical data registry 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 earn a PQRS incentive or avoid the PQRS payment adjustment. Therefore, we propose to modify § 414.90 to add paragraph (e)(2) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures, if the individual eligible professional satisfactorily participates in a qualified clinical data registry. This section also contains the criterion we are proposing for individual eligible professionals to meet to satisfactorily participate in a qualified clinical data registry for purposes of the 2016 PQRS payment adjustment.

We propose that, for purposes of the 2016 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2014), the exact same requirement we proposed above for satisfactory participation for the 2014 PQRS incentive. We believe it is appropriate to propose identical criteria for meeting the new standard for satisfactory participation given that the proposed 12-month reporting period for satisfactory participation in a qualified clinical data registry for the respective 2014 PQRS incentive and 2016 PQRS payment adjustments coincide.

We seek public comment on the proposed criterion for the satisfactory participation by individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment.

Tables 24 and 25 provide a summary of the proposed criteria for satisfactory reporting and satisfactory participation we discussed above for individual eligible professionals for the 2014 PQRS incentive and 2016 PQRS payment adjustment respectively.

TABLE 24—SUMMARY OF PROPOSALS FOR THE 2014 PQRS INCENTIVE: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF INDIVIDUAL QUALITY MEASURES VIA CLAIMS AND REGISTRIES AND PROPOSED SATISFACTORY PARTICIPATION CRITERION FOR INDIVIDUAL ELIGIBLE PROFESSIONALS IN QUALIFIED CLINICAL DATA REGISTRIES

Reporting period	Measure type	Reporting mechanism	Proposed satisfactory reporting criteria and satisfactory participation criteria
12-month (Jan 1–Dec 31) ...	Individual Measures	* Claims	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, OR, If less than 9 measures apply to the eligible professional, then the eligible professional must report 1–8 measures for which there is Medicare patient data; and Report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31) ...	Individual Measures	Qualified Registry	Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50% 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.
12-month (Jan 1–Dec 31) ...	Measures selected by Qualified Clinical Data Registry.	Qualified Clinical Data Registry.	Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50% of the eligible professional's patients. Of the measures reported via a clinical data registry, the eligible professional must report on at least 1 outcome measure.

*Subject to the MAV process.

TABLE 25—SUMMARY OF PROPOSALS FOR THE 2016 PQRS PAYMENT ADJUSTMENT: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF INDIVIDUAL QUALITY MEASURES VIA CLAIMS AND REGISTRIES AND PROPOSED SATISFACTORY PARTICIPATION CRITERION FOR INDIVIDUAL ELIGIBLE PROFESSIONALS IN QUALIFIED CLINICAL DATA REGISTRIES

Reporting period	Measure type	Reporting mechanism	Proposed satisfactory reporting and participation criteria
12-month (Jan 1–Dec 31) ...	Individual Measures	*Claims	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, OR, If less than 9 measures apply to the eligible professional, then the eligible professional must report 1–8 measures for which there is Medicare patient data; 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.
12-month (Jan 1–Dec 31) ...	Individual Measures	Registry	Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50% 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.
12-month (Jan 1–Dec 31) ...	Measures selected by the Qualified Clinical Data Registry.	Qualified Clinical Data Registry.	Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the eligible professional's patients. Of the measures reported via a clinical data registry, the eligible professional must report on at least 1 outcome measure.

*Subject to the MAV process.

7. Proposed Criteria for Satisfactory Reporting for the 2014 PQRS Incentive for Group Practices in the GPRO

For 2014, in accordance with § 414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. We finalized criteria for the satisfactory reporting for group practices participating in the GPRO for the 2014 PQRS incentive in the CY 2013 PFS final rule with comment period (see

Table 93, 77 FR 69195). In this section, we propose to change some of the criteria for satisfactory reporting for group practices under the GPRO using the registry and GPRO Web interface reporting mechanisms.

Group practices may currently report PQRS quality measures data to meet the criteria for satisfactory reporting for the 2014 PQRS incentive via the registry, EHR, and GPRO web interface reporting mechanisms. For the 2014 PQRS incentive, we finalized the following criterion for the satisfactory reporting of PQRS quality measures via the GPRO web interface for group practices comprised of 25–99 eligible professionals: Report on all measures included in the web interface; and populate data fields for the first 218 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 218, then report on 100 percent of assigned beneficiaries (77 FR 69195). We established this same criterion for the group practices of 25–99 eligible professionals for the 2013 PQRS incentive. Unfortunately, there has been low participation for this reporting option. We believe this is due to the fact that reporting using the GPRO web interface is more beneficial to larger practices because larger practices are better able to report on a more varied patient population. Therefore, to streamline the PQRS and eliminate reporting options that are largely unused, we propose to eliminate this criterion under the GPRO for the 2014 PQRS incentive. As a result, group practices comprised of 25–99 eligible professionals would no longer have the option to report PQRS quality measures using the GPRO web interface for the 2014 PQRS incentive. We do not believe this harms these smaller groups' practices, as group practices in the GPRO would still be able to report PQRS quality measures using either the registry or EHR-based reporting mechanisms.

For reporting under the GPRO using the registry-based reporting mechanism, we finalized the following criterion for the satisfactory reporting of PQRS quality measures for group practices comprised of 2 or more eligible professionals for the 2014 PQRS incentive in the CY 2013 final rule with comment period: Report at least 3 measures, and report each measure for at least 80 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 will not be counted (77 FR 69196). For the same reasons we are proposing to increase the number of measures an individual eligible must report as well as decrease the percentage threshold for individual eligible professionals reporting via registry for the 2014 PQRS incentive, we propose the following modified criteria for the satisfactory reporting of individual quality measures under the GPRO for the registry-based reporting mechanism: Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50% of the group practice's applicable seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

In addition, patient surveys are important tools for assessing beneficiary experience of care and outcomes. Many surveys are being used in both the private and public sectors, including the Medicare Health Outcomes Survey used by Medicare Advantage (MA) plans, Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey tools, and Health Resources Services Administration's (HRSA's) Health Center Patient Satisfaction Survey. Over the past two years, we have developed a Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for use with the Medicare Shared Savings Program and the PQRS. In 2012, we field tested the survey with a sample of 6,750 Medicare Fee-for-Service beneficiaries receiving care from nine group practices that participated in the Physician Group Practice Transition Demonstration. Subsequent to the field test, we refined the survey and in the spring of 2013 administered it for all Accountable Care Organizations (ACOs) participating in the Pioneer ACO program and the Medicare Shared Savings Program during 2012. More information about the survey is available at the **Federal Register** (77 FR 73032 and 78 FR 17676).

Because we believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, under our authority under section 1848(m)(3)(C)(i) of the Act to select the measures for which a group practice must report, we propose to provide group practices comprised of 25 or more eligible professionals with a new satisfactory reporting criterion that would include the option to complete the CG CAHPS survey along with reporting 6 other PQRS measures for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

We further propose that the survey would be administered following the close of the PQRS registration period. CMS also would provide each group a detailed report about the results of the survey. In addition, we propose to assign beneficiaries to a group practice using the same assignment methodology that we use for the GPRO web interface (77 FR 69195) . This method focuses on assigning beneficiaries to a group based on whether the group provided the plurality of primary care services. Because we propose to assign beneficiaries to a group based on the provision of primary care services, this survey is not an appropriate option for groups of physicians (for example, such as a group of surgeons) that do not provide primary care services. In accordance with section 1848(m)(3)(C)(ii) of the Act, which requires the GPRO to provide for the use of a statistical sampling model, we propose that the survey would be administered by certified survey vendor on behalf of the group practice for a sample of group's assigned beneficiaries. As noted earlier, to complete this survey, a group practice must indicate its intent to report the CG CAHPS survey when it registers to participate in the PQRS via the GPRO.

Please note that the CAHPS survey measures only cover 1 National Quality Strategy domain. In order to be consistent with other group practice reporting criteria we are proposing that require the reporting of measures covering at least 3 National Quality Strategy domains, we are proposing that, if a group practice reports the CAHPS measures via a certified survey vendor, the group practice would be required to report on at least 6 additional measures covering at least 2 National Quality Strategy domains.

Specifically, we are proposing the following criteria for satisfactory reporting for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, report all CAHPS survey measures via a certified vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

We seek public comment on our proposed criterion for the satisfactory reporting of data on these PQRS quality measures under the GPRO for the 2014 PQRS incentive.

8. Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Group Practices in the GPRO

This section addresses the proposed criteria for satisfactory reporting for group practices in the GPRO for the 2016 PQRS payment adjustment using the registry, GPRO web interface, and certified survey vendor reporting mechanisms. In the CY 2013 PFS final rule with comment period, we finalized the same criteria for satisfactorily reporting data on quality measures for the 2016 PQRS payment adjustment that apply for the 2014 PQRS incentive for the PQRS GPRO (77 FR 69200). We are making three of the same proposals for the criteria for satisfactory reporting under the GPRO for the 2016 PQRS payment adjustment that we are proposing for the 2014 PQRS incentive. Specifically, we propose to eliminate the following criterion for satisfactory reporting of PQRS quality measures via the GPRO web interface for group practices comprised of 25–99 eligible professionals: Report on all measures included in the web interface; and populate data fields for the first 218 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 218, then report on 100 percent of assigned beneficiaries. For the same reasons discussed previously and to maintain consistent criteria for the 2016 PQRS payment adjustment and 2014 PQRS incentive, we believe this proposed change is appropriate. We also note that if this proposal is finalized, only groups of 100 or more eligible professionals would be able to use the web interface reporting mechanism to report quality data under the GPRO.

Second, we propose to remove the following criterion for satisfactory reporting via registry under the GPRO for the 2016 PQRS payment adjustment: Report at least 3 measures, and report each measure for at least 80 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 will not be counted. This would allow us to maintain consistent criteria for the 2016 PQRS payment adjustment and 2014 PQRS incentive.

Consistent with our proposal to provide group practices comprised of 25 or more eligible professionals with a new satisfactory reporting criterion that would include the option to complete the CG CAHPS survey along with reporting 6 other PQRS measures for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive, we also propose the same criterion for purposes of meeting the criteria for satisfactory reporting for the 2016 PQRS payment adjustment. Specifically, we are proposing the following criteria for satisfactory reporting for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2016 PQRS payment adjustment, report all CAHPS survey measures via a certified vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms. As noted earlier, to complete this survey, a group practice must indicate its intent to report the CG CAHPS survey when it registers to participate in the PQRS via the GPRO.

In addition, we are proposing the same criteria for satisfactory reporting of individual quality measures under the GPRO for the registry-based reporting mechanism for the 2016 PQRS payment adjustment that we proposed above for the 2014 PQRS Incentive: Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted. In addition to the reasons we noted previously for modifying the existing registry satisfactory reporting criterion to increase the number of measures reported from 3 to 9, we believe it is appropriate to continue to align, as closely as possible, the criteria for satisfactory reporting for both the 2016 PQRS payment adjustment and 2014 PQRS Incentive.

We note that the criteria for satisfactory reporting under the GPRO for the 2014 PQRS incentive and the 2016 PQRS payment adjustment would align (such that a group practice would avoid the 2016 PQRS payment adjustment by meeting any of the criteria for satisfactory reporting adopted for the 2014 PQRS incentive for the 12-month reporting period). We believe this is appropriate since the reporting period for the 2014 PQRS incentive and 2016 PQRS payment adjustment coincide. We seek public comment on these proposals as well as on whether we should offer alternative criteria for group practices participating in the PQRS GPRO to satisfy the 2016 PQRS payment adjustment similar to what we have established for individual eligible professionals reporting via claims.

Tables 26 and 27 provides a summary of our proposed criteria for the satisfactory reporting of data on PQRS quality measures via the GPRO for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

TABLE 26—SUMMARY OF PROPOSALS FOR THE 2014 PQRS INCENTIVE: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criteria
12-month (Jan 1–Dec 31) ...	Qualified Registry	2 + eligible professionals ..	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31) ...	Certified Survey Vendor + Qualified Registry, direct EHR product, EHR data submission vendor, or GPRO web interface.	25+ eligible professionals ..	Report all CG CAHPS survey measures via certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

TABLE 27—SUMMARY OF PROPOSALS FOR THE 2016 PQRS PAYMENT ADJUSTMENT: PROPOSED CRITERIA FOR SATISFACTORY REPORTING OF DATA ON PQRS QUALITY MEASURES VIA THE GPRO

Reporting period	Reporting mechanism	Group practice size	Proposed reporting criteria
12-month (Jan 1–Dec 31) ...	Qualified Registry	2 + eligible professionals ..	Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31) ...	Certified Survey Vendor + Qualified Registry, direct EHR product, EHR data submission vendor, or GPRO web interface.	25+ eligible professionals ..	Report all CG CAHPS survey measures via certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

9. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2013 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 for 2014 and beyond. 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 reporting 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 (currently, that is the National Quality Forum, or 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 AQA alliance. 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) (that is, the NQF) and are silent for how the measures that are submitted to the NQF for endorsement were 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 needs to be any 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 entity with a contract with the Secretary under subsection 1890(a) of the Act (currently that, is the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of certain categories of quality and efficiency 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. Pursuant to section 3014 of Affordable Care Act, the NQF convened multi-stakeholder groups by creating the Measure Applications Partnership (MAP). Section 1890(A)(a) of the Act requires that the Secretary establish a pre-rulemaking process in which 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 selecting measures by February 1st of each year. The list of measures under consideration for 2013 is 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:

- High impact on healthcare.
- Measures that are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.
- Measures that address gaps in the quality of care delivered to Medicare beneficiaries.
- Address Gaps in the PQRS measure set.
- Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal).

• Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.).
• Broadly applicable measures that could be used to create a core measure set required of all participating eligible professionals.
• Measures groups that reflect the services furnished to beneficiaries by a particular specialty.

10. 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 2014 and beyond. We are classifying all proposed measures against six domains based on the National Quality Strategy's six priorities, as follows:

(1) *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 through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(2) *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

(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.

(4) *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. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

(5) *Efficiency and Cost Reduction.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

(6) *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

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 2013 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 were proposed 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 intend to 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 more substantive changes to measures that result in what are considered new or different measures, and that they 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*.

With respect to the PQRS EHR measures that are also reportable under the EHR Incentive Program (i.e., electronically specified clinical quality measures), please note that the updates to these measures will be provided on the EHR Incentive Program Web site. We understand that the EHR Incentive Program may accept versions of electronically specified clinical quality measures that may be outdated. We propose that for purposes of the PQRS, eligible professionals must report the most recent, updated version of a clinical quality measure. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures that are electronically specified using versions of the electronic specifications that were updated and posted on June 2013, available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. We also understand, for purposes of the EHR Incentive Program, that once direct EHR products and EHR data submission vendors are issued a 2014 Edition certification for clinical quality measures, they will not necessarily be required to have such technology retested and recertified against the most recent, updated version of a clinical quality measure when such versions are made available. We propose that for purposes of PQRS, however, that the eligible professional's direct EHR product or EHR data submission vendor must be tested and certified to the most recent, updated version of an electronically specified clinical quality

measure. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures from direct EHR products or EHR data submission vendors that have been tested and certified to versions of the electronic specifications that were updated and posted on June 2013. We seek comment on our proposals to require eligible professionals to both use the most recent, updated version of an electronically specified clinical quality measure to report for PQRS and to use a direct EHR product or EHR data submission vendor that has been tested and certified to the most recent, updated version of the clinical quality measure's electronic specifications for PQRS purposes.

a. Proposed Individual PQRS Measures and Measures Within Measures Groups Available for Reporting for 2014 and Beyond

(1) Proposed PQRS Core Measures Available for Reporting for 2014 and Beyond

In the CY 2013 PFS final rule with comment period, we finalized the HHS Million Hearts Measures as a recommended set of core measures for which we encourage eligible professionals to report in PQRS (77 FR 69209). In addition to the HHS Million Hearts Measures we previously finalized, we are proposing to include the measures specified in Table 28 as additional recommended core measures for 2014 and beyond (in the table we also identify the applicable PQRS reporting mechanism through which each measure could be submitted). These additional proposed recommended core measures were also finalized as recommended core measures in the EHR Incentive Program for 2014. Therefore, due to our desire to align with the recommended measures available under the EHR Incentive Program, we are proposing the additional recommended measures specified in Table 28 for 2014 and beyond.

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TABLE 28: Proposed Physician Quality Reporting System Recommended Core Measures for 2014 and Beyond

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0002/66**	146v2	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode. A higher rate represents better performance (i.e. appropriate testing).	NCQA		X	X			MU2
0018/236*	165v2	Effective Clinical Care	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA	X	X	X	X	X	MU2 ACO Million Hearts
0022/238*	156v2	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.	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0024/239**	155v2	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity	NCQA			X			MU2
0028/226*	138v2	Community/ Population Health	**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	X	X	X	X	X	MU2 ACO Million Hearts
0033/310**	153v2	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women aged 15 through 24 years who were identified as sexually active and who had at least one test for chlamydia during the measurement year	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0036/311**	126v2	Effective Clinical Care	**Use of Appropriate Medications for Asthma:** Percentage of patients aged 5 through 50 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year	NCQA			X			MU2
0038/240**	117v2	Community/ Population Health	**Childhood Immunization Status:** The percentage of children two years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV); one measles, mumps, rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	NCQA			X			MU2
0052/312*	166v2	Efficiency and Cost Reduction	**Use of Imaging Studies for Low Back Pain:** Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	NCQA			X			MU2
0069/65**	154v2	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	NCQA		X	X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0108/N/A**	136v3	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	NCQA			X			MU2
0418/134***	2v2	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.	CMS	X	X	X	X		MU2 ACO

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0419/130*	68v2	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS	X	X	X		X	MU2
0421/128*	69v1	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23 and < 30; Age 18 – 64 years BMI ≥ 18.5 and < 25	CMS	X	X	X	X	X	MU2 ACO
N/A/N/A**	75v2	Effective Clinical Care	**Children who have dental decay or cavities:** Percentage of children ages, 0-20 years, who have had tooth decay or cavities during the measurement period	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A*	50v2	Communication and Care Coordination	**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	CMS			X			MU2
N/A/N/A*	90v3	Person and Caregiver-Centered Experience and Outcomes	**Functional status assessment for complex chronic conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments	NQF			X			MU2

* Recommended Adult Core CQMs for eligible professionals

** Recommended Pediatric Core CQMs for eligible professionals

¥ Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ from existing measures in other programs. When reporting data on these measures, please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

(2) Proposed Individual PQRS Measures Available for Reporting for 2014 and Beyond

Table 29 contains the measures we are proposing to include in the PQRS measure set for 2014 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.

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TABLE 29: Proposed Individual Quality Measures and Those Included in Measures Groups for the Physician Quality Reporting System to be Available for Satisfactory Reporting via Claims, Registry, or EHR Beginning in 2014

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0060/N/A	148v2	Effective Clinical Care	**Hemoglobin A1c Test for Pediatric Patients:** Percentage of patients 5-17 years of age with diabetes with an HbA1c test during the measurement period **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. Furthermore, including this measure in the PQRS measure set is in accordance with our intention to align with the measures included in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2
0108/N/A	136v3	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. We are proposing this measure for inclusion in PQRS because this measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0403/N/A	62v2	Efficiency and Cost Reduction	**HIV/AIDS: Medical Visit:** Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 90 days between each visit **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. We are proposing this measure for inclusion in PQRS because this measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2
0110/N/A	169v1	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for Alcohol or Chemical Substance Use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CQAIMH			X			MU2
0608/N/A	158v2	Effective Clinical Care	**Pregnant Women that had HBsAg Testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	OptumInsight			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0710/N/A	159v2	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 measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	MNCM			X			MU2
0712/N/A	160v2	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	MNCM			X			MU2
1401/N/A	82v1	Community/ Population Health	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	NCQA			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	65v3	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	50v2	Communication and Care Coordination	**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:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	66v2	Effective Clinical Care	**Functional Status Assessment for Knee Replacement:** Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	56v2	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Hip Replacement:** Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	90v3	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Complex Chronic Conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	75v2	Effective Clinical Care	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	74v3	Effective Clinical Care	**Primary Caries Prevention Intervention as offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
N/A/N/A	179v2	Patient Safety	**ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range:** Average percentage of time in which patients aged 18 and older with atrial fibrillation who are on chronic warfarin therapy have International Normalized Ratio (INR) test results within the therapeutic range (i.e., TTR) during the measurement period **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
1365/N/A	177v2	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	AMA-PCPI			X			MU2
N/A/N/A	77v2	Effective Clinical Care	**HIV/AIDS: RNA Control for Patients with HIV:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL **Rationale:** We are proposing this measure based on our exception authority under 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 also included for reporting in the EHR Incentive Program for 2014. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program.	CMS			X			MU2
2082/N/A		Effective Clinical Care	**HIV Viral Load Suppression:** 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. **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program. It aligns to current clinical standards for treatment for patient with the chronic condition of HIV.	HRSA		X			X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
2083/N/A		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:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program. It aligns to current clinical standards for treatment for patient with the chronic condition of HIV.	HRSA		X			X	
2079/N/A		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:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is in alignment with the HHS/HRSA strategy for having a core set of HIV measures.	HRSA					X	
2080/N/A		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 month of the measurement year **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure is in alignment with the HHS/HRSA strategy for having a core set of HIV measures.	HRSA					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or older with at least one adenoma or other colorectal cancer precursor or colorectal cancer detected during screening colonoscopy **Rationale:** We are proposing this measure based on our exception authority under 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 broad patient population for screening and detection of colorectal cancer and is medically significant in the measurement of utilizing preventive healthcare services. The individual measure is reportable for Gastroenterologist and other eligible professionals within this scope of practice. Currently, PQRS has 2 specific measures that are applicable to this scope of practice.	ACGAGA/ ASGE		X				
N/A/N/A		Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. NSAIDs, analgesics, exercise, injections) prior to the procedure **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients 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 (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Total Knee Replacement Measures Group. This measures group provides eligible professionals opportunity to report assessments prior to a total knee surgery such as shared decision-making reviewing conservative therapy prior to invasive surgery, risk assessment, prophylactic antibiotic prior to tourniquet inflation, and identification of prosthesis implant within medical chart. This measures group allows Orthopedic Surgeons and other eligible professionals within this scope of practice a measures group to report.	AAHKS/ AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**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 institutions computer systems **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows specialty Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**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 **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**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 **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**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 **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**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 (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Optimizing Patient Exposure to Ionizing Radiation Measures Group. This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/ comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This measures group allows speciality Radiologist and other eligible professionals within this scope of practice a measures group to report.	AMA-PCPI					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**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:** We are proposing this measure based on our exception authority under 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 be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as bleeding and could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of postoperative stroke or death in Asymptomatic Patients undergoing Carotid Endarterectomy (CEA):** Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital **Rationale:** We are proposing this measure based on our exception authority under 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 be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as stroke and could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of postoperative stroke or death in Asymptomatic Patients undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital **Rationale:** We are proposing this measure based on our exception authority under 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 be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as stroke. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Rate of Major Complications (Discharged to Home by Post- Operative Day #2) Carotid Artery Stenting (CAS) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post- operative day #2 **Rationale:** We are proposing this measure based on our exception authority under 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 be reported by Vascular Surgical eligible professionals. Currently, PQRS has 5 specific measures that are applicable to this scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record or #131: Pain Assessment and Follow-Up. This measure would produce data that evaluates procedural death and sequela events such as stroke. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure represents an outcome measure for this specific specialty.	SVS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Vascular Composite:** Optimal Vascular Care: Patients ages 18 to 75 with ischemic vascular disease (IVD) who meet all of the numerator targets of this composite measure: LDL less than 100, Blood Pressure less than 140/90, Tobacco-Free Status, and Daily Aspirin Use (unless contraindicated) **Rationale:** We are proposing this measure based on our exception authority under 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 composite measure encompasses measurements that address risk factors for this specific patient population. This composite measure would be able to be reported by a variety of eligible professionals ranging from Family Practice to Vascular and potentially Cardiologist.	MNCM		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Physician-specific risk-standardized rates of procedural complications following the implantation of an ICD **Rationale:** We are proposing this measure based on our exception authority under 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). Electrophysiologists and eligible professionals within this scope of practice would report this measure. Currently, PQRS does not contain any measures that are specific to this scope of practice. It may be possible for these eligible professionals to report on general measures such as #130: Documentation of Current Medications in the Medical Record. CMS recognizes that PQRS contains measures that are clinically heart related, but concedes that these measures may be more relevant to General Cardiology rather than Electrophysiology. This measure would produce data that evaluates procedural death and sequela events such as lead dislodgement. This data could allow eligible professionals reporting to "benchmark" patient health post procedure. This measure represents an outcome based measure.	HRS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0209/N/A		Person and Caregiver-Centered Experience and Outcomes	**Pain Brought under Control within 48 Hours:** Number of patients who report being uncomfortable because of pain at the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. This measure concept would be new for PQRS. There are no measures currently within the program that address care for patients that are being managed by palliative care or eligible professionals that would provide these services to patients. Pain management for patients receiving palliative care would add beneficial data to a medical concept that currently has no measurement available within this program.	NHPCO		X				
N/A/N/A		Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis Access is a Catheter at the Time Maintenance Hemodialysis is Initiated:** Percentage of patients aged 18 years and older with a diagnosis of ESRD who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is via a catheter at the time maintenance hemodialysis is initiated **Rationale:** We are proposing this measure based on our exception authority under 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 expands upon the care that is represented in adult kidney disease patient population. It allows eligible professionals providing care for these patients a greater variety of measures to report. PQRS currently has 5 adult kidney disease and 2 pediatric kidney disease individual measures for reporting. PQRS also currently has an Adult Kidney Disease Measures Group available to report.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Adult Kidney Disease: Catheter Use for Greater than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter **Rationale:** We are proposing this measure based on our exception authority under 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 expands upon the care that is represented in adult kidney disease patient population. It allows eligible professionals providing care for these patients a greater variety of measures to report. PQRS currently has 5 adult kidney disease and 2 pediatric kidney disease individual measures for reporting. PQRS also currently has an Adult Kidney Disease Measures Group available to report.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**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 **Rationale:** We are proposing this measure based on our exception authority under 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 new medical concept within PQRS. The measure is reportable by Ear, Nose and Throat (ENT) and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures in the program within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Acute Bacterial Sinusitis (Appropriate Use):** 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:** We are proposing this measure based on our exception authority under 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). These measures represent a new medical concept within PQRS. The measure is reportable by ENT and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Efficiency and Cost Reduction	**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 **Rationale:** We are proposing this measure based on our exception authority under 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). These measures represent a new medical concept within PQRS. The measure is reportable by ENT and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Efficiency and Cost Reduction	**Adult Sinusitis: More than 1 Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered at the time of diagnosis or received within a 90 day period after date of diagnosis **Rationale:** We are proposing this measure based on our exception authority under 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). These measures represent a new medical concept within PQRS. The measure is reportable by ENT and other eligible professionals within this specific scope of practice. ENT eligible professionals have a limited number of measures within their scope of practice. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures would also be reportable by Family Physicians, Internal Medicine and other related eligible professionals within those scopes of practice.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at >=37 and < 39 weeks (Overuse):** 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:** We are proposing this measure based on our exception authority under 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 new medical concept within PQRS. These individual measures are reportable by Obstetrics/Gynecologist and other eligible professionals within this specific scope of practice. They currently have a limited number of measures, including urinary incontinence, within their scope of practice. This measure would allow this specialty type of eligible professional the opportunity to report upon a specific patient sample directly related to mother/baby. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures could also possibly be reportable by Family Physicians and other related eligible professionals in a rural setting where this is seen more often. This measure represents an outcome measure.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Communication and Care Coordination	**Maternity Care: Post-Partum Follow-Up and Communication 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:** We are proposing this measure based on our exception authority under 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 new medical concept within PQRS. These individual measures are reportable by Obstetrics/Gynecologist and other eligible professionals within this specific scope of practice. They currently have a limited number of measures, including urinary incontinence, within their scope of practice. This measure would allow this specialty type of eligible professionals the opportunity to report upon a specific patient sample directly related to mother/baby. PQRS does include other general measures that would be potentially applicable for these eligible professionals to report, such as measure #130: Documentation of Current Medications in the Medical Record and/or #317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. These measures could also possibly be reportable by Family Physicians and other related eligible professionals in a rural setting where this is seen more often. This measure represents an outcome measure.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**Atopic Dermatitis: Overuse: Role of Antihistamine:** Percentage of patients aged 25 years or younger seen at one or more visits within a 12-month period with a diagnosis of atopic dermatitis, who did not have a diagnosis of allergic rhinitis or urticaria, who were prescribed oral nonsedating antihistamines **Rationale:** We are proposing this measure based on our exception authority under 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). Atopic dermatitis is a new medical concept for reporting within PQRS. This would provide Dermatology and other related eligible professionals with an additional measure to report within PQRS. Dermatologists could also report upon general measures such as measure #130: Documentation of Current Medications in the Medical Record.	AMA-PCPI		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Tuberculosis Prevention for Psoriasis and Psoriatic Arthritis Patients on a Biological Immune Response Modifier:** This measure evaluates whether providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test **Rationale:** We are proposing this measure based on our exception authority under 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). Psoriasis is a new medical concept for reporting within PQRS. This measure would provide Dermatology and other related eligible professionals an additional measure to report within PQRS. This measure could also be reported by other professionals that treat joint care such as Family Practice and Rheumatologists. Other than the Family Practice, the other specialists listed above are limited in the currently PQRS measures. They could report general measures such as measure #130: Documentation of Current Medications in the Medical Record.	AAD		X					
N/A/N/A		Effective Clinical Care	**Neurosurgery: Initial Visit:** The percentage of patients aged 18 through 80 years with a diagnosis of a neurosurgical procedure or pathology who had function assessed during the initial visit to the clinician for the episode of the condition **Rationale:** We are proposing this measure based on our exception authority under 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 be most applicable to Neurologists and Neurosurgeons and other eligible professionals within this scope of practice. There are currently no measures in the PQRS program that are reportable for this scope of practice. This measure may represent a broad patient sample.	AANS/CNS		X					

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality **Rationale:** We are proposing this measure based on our exception authority under 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 be broadly applicable to a variety of surgical eligible professionals and could potentially allow reporting in surgical settings not currently available within PQRS. PQRS currently includes Perioperative surgical measures and a Perioperative Measures Group, but the procedures included in those denominators are limited to certain types of procedures or determination of pre-procedure indications such as prophylactic antibiotics. Clinically, not all surgeries are indicated for prophylactic antibiotics. This measure would potentially not have any clinical limitations.	ACS		X				

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Iatrogenic Injury to Adjacent Organ/Structure:** Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect **Rationale:** We are proposing this measure based on our exception authority under 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). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy would allow surgeons another opportunity to report via measures group reporting. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. This measure set would produce data that specifically evaluate procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy **Rationale:** We are proposing this measure based on our exception authority under 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). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluates procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients age 65 and older who had a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such **Rationale:** We are proposing this measure based on our exception authority under 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). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluates procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Surgical Site Infection (SSI):** Percentage of patients age 65 and older who had a surgical site infection **Rationale:** We are proposing this measure based on our exception authority under 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). Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluates procedural endpoints such as iatrogenic injury to adjacent organ, unplanned reoperation within 30 days, unplanned readmission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the General Surgery Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Iatrogenic Injury to Adjacent Organ/Structure:** Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Anastomotic Leak Intervention:** Percentage of patients age 65 and older who had an intervention (via return to operating room, interventional radiology, or interventional gastroenterology) for presence of leak of endoluminal contents (such as air, fluid, GI contents, or contrast material) through an anastomosis. The presence of an infection/abscess thought to be related to an anastomosis, even if the leak cannot be definitively identified as visualized during an operation, or by contrast extravasation would also be considered an anastomotic leak **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients age 65 and older who had a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Surgical Site Infection (SSI):** Percentage of patients age 65 and older who had a surgical site infection **Rationale:** We are proposing this measure based on our exception authority under 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 contained within the Gastrointestinal (GI) Measures Group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. These measures would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, unplanned reoperation within 30 days, unplanned hospital admission within 30 days, and site infection. This data could allow eligible professionals reporting to "benchmark" patient health post-surgery or procedure. This measure contained within the Gastrointestinal (GI) Measures Group is an outcome measure specifically relevant to these general surgery procedures.	ACS					X	

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0147/N/A		Patient Safety	**PN-6: Initial Antibiotic Selection for CAP in Immunocompetent** **Patient:** Immunocompetent patients with Community-Acquired Pneumonia who receive an initial antibiotic regimen during the first 24 hours that is consistent with current guidelines **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR
0372/N/A		Patient Safety	**VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis:** This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure set addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	The Joint Commission		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A		Patient Safety	**VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol:** This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol. **Rationale:** We are proposing this measure based on our exception authority under 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). CMS believes this measure set addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	The Joint Commission		X				IQR
0495/N/A		Communication and Care Coordination	**ED-1a: Median Time from ED Arrival to ED Departure for Admitted ED Patients - Overall Rate:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients assessed in the emergency department (ED). This measure would provide statistical data representing individual eligible professionals providing and coordinating medical care for patients seeking medical attention from the emergency department. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0495/N/A		Communication and Care Coordination	**ED-1d: Median Time from ED Arrival to ED Departure for Admitted Patients - Psychiatric/Mental Health Patients:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients assessed in the emergency department (ED). This measure would provide statistical data representing individual eligible professionals providing and coordinating medical care for patients seeking medical attention from the emergency department. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
1659/N/A		Community/ Population Health	**IMM-1c: Pneumococcal Immunization (PPV23) – High Risk Populations (Age 5 through 64 years):** This prevention measure addresses acute care hospitalized inpatients 65 years of age and older (IMM-1b) AND inpatients aged between 5 and 64 years (IMM-1c) who are considered high risk and were screened for receipt of pneumococcal vaccine and were vaccinated prior to discharge if indicated. The numerator captures two activities; screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to pneumococcal vaccine, patients who were offered and declined pneumococcal vaccine and patients who received pneumococcal vaccine anytime in the past are captured as numerator events. **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. The measure represented would provide statistical data representing population and community health for patients within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	CMS		X				IQR

NQF/PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0166/N/A		Communication and Care Coordination	**HCAHPS: Hospital Consumer Assessment of Healthcare Providers and Systems Survey:** 27-items survey instrument with 7 domain-level composites including: communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness and quiet of the hospital environment, and discharge information **Rationale:** This measure satisfies 1848(k)(2)(C)(i) of the Act as this measure is NQF-endorsed. CMS believes this measure addresses a performance gap for eligible professionals providing care to patients admitted within a hospital setting. This measure would provide statistical data representing person and caregiver-centered experience and outcomes for patients that have experienced care within a hospital setting. Including this measure from Hospital Inpatient Quality Reporting (IQR) in the PQRS measure set is in accordance with our intent to align measures throughout CMS reporting programs.	AHRQ		X				IQR

¥ Titles and descriptions in this table are aligned with proposed 2014 Health Information Technology for Economic and Clinical Health (HITECH) measure titles, and may differ from existing measures in other programs. When reporting data on these measures, please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

In Table 30, 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 30: Measures Proposed for Removal from the Existing Physician Quality Reporting System Measure Set Beginning in 2014

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0061/3	Effective Clinical Care	**Diabetes Mellitus: High Blood Pressure Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) **Rationale:** Eliminating duplicative measures within PQRS.	NCQA	X	X	X		X	MU1
N/A/86	Effective Clinical Care	**Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X			X	
N/A/89	Effective Clinical Care	**Hepatitis C: Counseling Regarding Risk of Alcohol Consumption:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X			X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/90	Effective Clinical Care	**Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy:** Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X			X	
N/A/161	Effective Clinical Care	**HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm^3 or who have a history of an AIDS-defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI/ NCQA		X			X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/162	Effective Clinical Care	**HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI/ NCQA		X			X	
AQA adopted/173	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, that does not have this measure available for reporting in 2014.	AMA-PCPI	X	X	X		X	
N/A/184	Community/ Population Health	**Hepatitis C: Hepatitis B Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/188	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a congenital or traumatic deformity of the ear (internal or external) **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AQC	X	X				
N/A/200	Effective Clinical Care	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Therefore, there measure will not be maintained for reporting beginning in 2014.	AMA-PCPI/ ACCF/AHA			X			MU1
0073/201	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Blood Pressure Management:** Percentage of patients aged 18 to 75 years with Ischemic Vascular Disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg) **Rationale:** Eliminating duplicative measures within PQRS.	NCQA	X	X	X		X	MU1

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0410/208	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months **Rationale:** Measure owner combined NQF 0410 with NQF 0409.	AMA-PCPI/ NCQA		X			X	
0445/209	Effective Clinical Care	**Functional Communication Measure - Spoken Language Comprehension:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Comprehension Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0449/210	Effective Clinical Care	**Functional Communication Measure – Attention:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Attention Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0448/211	Effective Clinical Care	**Functional Communication Measure – Memory:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Memory Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0447/212	Effective Clinical Care	**Functional Communication Measure - Motor Speech:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Motor Speech Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0446/213	Effective Clinical Care	**Functional Communication Measure – Reading:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Reading Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0444/214	Effective Clinical Care	**Functional Communication Measure - Spoken Language Expression:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Expression Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0442/215	Effective Clinical Care	**Functional Communication Measure – Writing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Writing Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				
0443/216	Effective Clinical Care	**Functional Communication Measure – Swallowing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Swallowing Functional Communication Measure **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ASHA		X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0013/237	Effective Clinical Care	**Hypertension (HTN): Blood Pressure Measurement:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	AMA-PCPI			X			
N/A/244	Effective Clinical Care	**Hypertension: Blood Pressure Management:** Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more anti-hypertensive medications during the most recent office visit **Rationale:** Measure deletion due to duplicative measures within PQRS.	AMA-PCPI/ ACCF/AHA		X				
0503/252	Effective Clinical Care	**Anticoagulation for Acute Pulmonary Embolus Patients:** Anticoagulation ordered for patients who have been discharged from the emergency department (ED) with a diagnosis of acute pulmonary embolus **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	ACEP	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/256	Communication and Care Coordination	**Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR):** Percentage of patients 18 years of age or older undergoing endovascular abdominal aortic aneurysm repair (EVAR) who have at least one follow-up imaging study after 3 months and within 15 months of EVAR placement that documents aneurysm sac diameter and endoleak status **Rationale:** Measure lost Measure Owner support. Therefore, there measure will not be maintained for reporting beginning in 2014.	SVS		X				
0012/306	Community/Population Health	**Prenatal Care: Screening for Human Immunodeficiency Virus (HIV):** Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	AMA-PCPI			X			MU1
0014/307	Patient Safety	**Prenatal Care: Anti-D Immune Globulin:** Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	AMA-PCPI			X			MU1

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0027/308	Community/Population Health	**Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies:** Percentage of patients aged 18 years and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	NCQA			X			MU1
0575/313	Effective Clinical Care	**Diabetes Mellitus: Hemoglobin A1c Control (< 8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8% **Rationale:** We are deleting this measure to align with the measures available under the EHR Incentive Program, which does not have this measure available for reporting in 2014.	NCQA			X			

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0493/321	Communication and Care Coordination	**Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry. b. Data elements are applicable to consensus endorsed quality measures. c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure. f. Registry may provide feedback directly to the provider's local registry if one exists. **Rationale:** Due to the proposed inclusion of Qualified Clinical Data Registries, we believe this measure is redundant. Therefore, CMS is proposing to remove this measure.	OFMQ	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Communication and Care Coordination	**Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits **Rationale:** Measure Owner decision to remove this measure from Total Knee Replacement and replace with the measure: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy	AAHKS/ AMA-PCPI					X	
N/A/N/A	Person and Caregiver-Centered Experience and Outcomes	**Chronic Wound Care: Patient Education Regarding Long-Term Compression Therapy:** Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy including interval replacement of compression stockings within the 12 month reporting period **Rationale:** This measure concept is routinely met in a clinical setting. CMS believes it would not indicate a true quality outcome.	AMA-PCPI	X	X				

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months **Rationale:** Propose to delete this measures group due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Patient Safety	**Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months **Rationale:** Propose to delete this measures group due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Osteoporosis: Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months **Rationale:** Propose to delete this measures group due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Osteoporosis: Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal:** Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines:** Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a three-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a three-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a three-month grace period) for patients with ≤ 1 risk factor for CHD) **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Diabetes Documentation or Screen Test:** Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program.	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Counseling for Diet and Physical Activity:** Percentage of patients who received dietary and physical activity counseling **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI):** Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	

NQF/PQRS	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy:** Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10% **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Smoking Status and Cessation Support:** Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period. **Rationale:** This measures group is proposed for deletion due to the amount of measures that have duplicative medical concepts within the PQRS program	ABIM					X	

¥ Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

b. Proposed 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.'' As we discussed in section IV.I.4. above, we propose to increase the number of measures reported by individual eligible professionals via claims and registry from 3 to 9. Since we are proposing to increase the number of individual measures to be reported via claims and registry, we believe it is also appropriate to increase the number of measures that would be reported in a measures group. Specifically, we propose to modify the minimum amount of measures that may be included in a PQRS measures group from four to six. Therefore, we are proposing to modify the definition of a measures group at § 414.90(b) to indicate that a measures group would consist of at least six measures. Consequently, we are proposing to add additional measures to measures groups that previously contained less than six measures. We believe that, although it is appropriate to increase the number of measures in a measures group, we do not believe it would be appropriate to increase the minimum number of reportable measures in a measures group to 9, such as we are proposing for individual eligible professionals who report individual quality measures via claims and registry. Unlike reporting individual measures, where an eligible professional would be able to report on any 9 measures of his/her choosing, an eligible professional is required to report on ALL the measures contained in a measures group. We believe increasing the number of minimum measures in a measures group to six is reasonable, as it would only require the eligible professional to report on an additional two measures.

Tables 31 through 53 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 (77 FR 69272).

In addition to the measures groups that we finalized for 2013 and beyond, we are proposing the following three additional measures groups, which are identified in Tables 54 through 56:

- *Optimizing Patient Exposure to Ionizing Radiation:* This measures group represents a new clinical theme for eligible professionals to report and addresses a clinical gap. This measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This would be a measures group that specialty Radiologists and other eligible professionals within this scope of practice could report.

- *General Surgery:* Addition of a General Surgery Measures Group including procedures such as ventral hernia, appendectomy, AV fistula, cholecystectomy, thyroidectomy, mastectomy, lymphadenectomy, sentinel lymph node biopsy (SLNB), or lumpectomy/breast biopsy would allow surgeons another opportunity to report via measures group reporting.

- *Gastrointestinal Surgery:* This measures group could be reported by specialized general surgical eligible professionals that focus on bariatric and colectomy procedures. PQRS currently has another measures group in which Surgeons and other eligible professionals may report: Perioperative Measures Group. However, these measures address a gap in that it would produce data that specifically evaluate iatrogenic injury to adjacent organ, anastomotic leak intervention, and unplanned reoperation.

Please note that, since we are proposing to eliminate the option to report measures groups via claims, all measures groups proposed for 2014 and beyond would be reportable through registry-based reporting only.

¥ Titles and descriptions in these tables are aligned with the 2014 Physician Quality Reporting System Claims and Registry measure titles and descriptions, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

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TABLE 31: Proposed Diabetes Mellitus Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0059/ 1	**Diabetes Mellitus: Hemoglobin A1c Poor Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	NCQA
0064/ 2	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA
0055/ 117	**Diabetes Mellitus: Dilated Eye Exam:** Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period	NCQA
0062/ 119	**Diabetes Mellitus: Urine Protein Screening:** 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
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0056/ 163	**Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination	NCQA

TABLE 32: Proposed Chronic Kidney Disease (CKD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0041/ 110	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI
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

AQA adopted /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
1666/123	**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	AMA-PCPI
0419/130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
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 33: Proposed Preventive Care Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0046/39	**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
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	**Preventive Care and Screening: Pneumococcal Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA

0031/ 112	**Preventive Care and Screening: Breast Cancer Screening:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months	NCQA
0034/ 113	**Preventive Care and Screening: Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening	NCQA
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25	CMS
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 34: Proposed Coronary Artery Bypass Graft (CABG) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0134/ 43	**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/ 44	**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
0115/168	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	STS
0116/169	**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	STS
0117/170	**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	STS
0118/171	**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	STS

TABLE 35: Proposed Rheumatoid Arthritis (RA) Measures Group for 2014 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
AQA adopted /176	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of 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
AQA adopted /177	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months	AMA-PCPI
AQA adopted /178	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months	AMA-PCPI
AQA adopted /179	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months	AMA-PCPI
AQA adopted /180	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for glucocorticoid use and, for those on prolonged doses of	AMA-PCPI

NQF/ PQRS	Measure Title and Description	Measure Developer
	prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	

TABLE 36: Proposed Perioperative Care Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0270/ 20	**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, two hours), prior to the surgical incision (or start of procedure when no incision is required)	AMA-PCPI/ NCQA
0268/ 21	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis	AMA-PCPI/ NCQA
0271/ 22	**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	AMA-PCPI/ NCQA
0239/ 23	**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	AMA-PCPI/ NCQA
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS

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	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

TABLE37: Proposed Back Pain Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0420/ 131	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment through discussion with the patient including the use of a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	CMS
0322/ 148	**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	NCQA
0319/ 149/	**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	NCQA
0314/ 150	**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	NCQA
0313/ 151	**Back Pain: Advice Against Bed Rest:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain	NCQA

TABLE 38: Proposed Hepatitis C Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0395/ 84	**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 are receiving antiviral treatment for whom quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment	AMA-PCPI
0396/ 85	**Hepatitis C: HCV Genotype Testing Prior to Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom HCV genotype testing was performed prior to initiation of antiviral treatment	AMA-PCPI
0398/ 87	**Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing at Week 12 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 HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment	AMA-PCPI
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
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 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

TABLE 39: Proposed Heart Failure (HF) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0081/ 5	**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/ 8	**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
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25	CMS
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0079/ 198	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12 month period	AMA-PCPI/ ACCF/ AHA
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 40: Proposed Coronary Artery Disease (CAD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0067/ 6	**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
0421/ 128	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25	CMS
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0074/ 197	**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	AMA-PCPI/ ACCF/ AHA
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 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 41: Proposed Ischemic Vascular Disease (IVD) Measures Group for 2014 and Beyond

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 an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**.	CMS
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0068/ 204	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or another antithrombotic	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
0018/ 236	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA
0075/ 241	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA

TABLE 42: Proposed HIV/AIDS Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0404/ 159	**HIV/AIDS: CD4+ Cell Count or CD4+ Percentage:** 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	AMA-PCPI/ NCQA
0405/ 160	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 years and older with a diagnosis of HIV/AIDS and CD4+ cell count < 200 cells/mm^3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count	AMA-PCPI/ 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 and who were screened for syphilis at least once within 12 months	AMA-PCPI/ NCQA
2082/ N/A	**HIV Viral Load Suppression:** 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/ N/A	**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/ N/A	**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
2080/ N/A	**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 month of the measurement year	HRSA

TABLE 43: Proposed Asthma Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0047/ 53	**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. Three rates are reported for this measure: 1. Patients prescribed inhaled corticosteroids (ICS) as their long term control medication. 2. Patients prescribed other alternative long term control medications (non-ICS). 3. Total patients prescribed long-term control medication	AMA-PCPI/ NCQA
0001/ 64	**Asthma: Assessment of Asthma Control – Ambulatory Care Setting:** Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least once during the measurement period for asthma control (comprising asthma impairment and asthma risk)	AMA-PCPI/ NCQA
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 specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
N/A/ 231	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma 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	AMA-PCPI/ NCQA
N/A/ 232	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting:** Percentage of patients (or their primary caregiver) aged 5 through 50 years with a diagnosis of asthma who were identified as tobacco users (patients who currently use tobacco AND patients who do not currently use tobacco, but are exposed to second hand smoke in their home environment) who received tobacco cessation intervention at least once during the one-year measurement period	AMA-PCPI/ NCQA

TABLE 44: Proposed Chronic Obstructive Pulmonary Disease (COPD) Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0091/ 51	**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/ 52	**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
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
0043/ 111	**Preventive Care and Screening: Pneumococcal Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI

TABLE 45: Proposed Inflammatory Bowel Disease (IBD) Measures Group for 2014 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/ 269	**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	AGA

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
N/A/ 272	**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	AGA
N/A/ 273	**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	AGA
N/A/ 274	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA
N/A/ 275	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA

TABLE 46: Proposed Sleep Apnea Measures Group for 2014 and Beyond

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 an encounter during the reporting period with a documented calculated BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, follow-up is documented during the encounter or during the previous six months of the encounter with the BMI **outside of normal parameters**. **Normal Parameters:** Age 65 years and older BMI $\geq$ 23and $<$ 30; Age 18 – 64 years BMI $>$ 18.5 and $<$ 25	CMS

0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	CMS
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 Dementia Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
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 patient's 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 patient's 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 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 48: Proposed Parkinson's Disease Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
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 49: Proposed Hypertension Measures Group for 2014 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/ 295	**Hypertension: Appropriate 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	ABIM
N/A/ 296	**Hypertension: Complete Lipid Profile:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within **60 months**	ABIM
N/A/ 297	**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**	ABIM
N/A/ 298	**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
N/A/ 299	**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**	ABIM
N/A/ 300	**Hypertension: Blood Pressure Control:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (< 140/90 mmHG)	ABIM
N/A/ 301	**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)	ABIM

N/A/ 302	**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**	ABIM

TABLE 50: Proposed Cardiovascular Prevention Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0064/ 2	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA
0068/ 204	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or another antithrombotic	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
0018/ 236	**Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose BP was adequately controlled (< 140/90 mmHg)	NCQA
0075/ 241	**Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and whose most recent LDL-C level was in control (less than 100 mg/dL)	NCQA
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 51: Proposed Cataracts Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL	CMS

	prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration	
0565/ 191	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery	AMA-PCPI/ NCQA
0564/ 192	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence	AMA-PCPI/ NCQA
0028/ 226	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI
N/A/ 303	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey	AAO
N/A/ 304	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey	AAO
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

TABLE 52: Proposed Oncology Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0387/ 71	**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/ 72	**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 specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL 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
0386/ 194	**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	AMA-PCPI/ ASCO
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 53: Proposed Total Knee Replacement Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL 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 / N/A	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. NSAIDs, analgesics, exercise, injections) prior to the procedure	AAHKS /AMA-PCPI
N/A / N/A	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients 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 (DVT), pulmonary embolism (PE), myocardial infarction (MI), arrhythmia and stroke	AAHKS /AMA-PCPI
N/A / N/A	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAHKS /AMA-PCPI
N/A / N/A	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant	AAHKS /AMA-PCPI

TABLE 54: Proposed Optimizing Patient Exposure to Ionizing Radiation Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
N/A/ N/A	**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 institutions computer systems	AMA-PCPI
N/A/ N/A	**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/ N/A	**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/ N/A	**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/ N/A	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external 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/ N/A	**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 55: Proposed General Surgery Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL 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/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Iatrogenic Injury to Adjacent Organ/Structure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect	ACS

N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Reoperation within the 30 Day Postoperative Period:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy	ACS
N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such	ACS
N/A/ N/A	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Surgical Site Infection (SSI):** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had a surgical site infection	ACS
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

TABLE 56: Proposed Gastrointestinal Surgery Measures Group for 2014 and Beyond

NQF/ PQRS	Measure Title	Measure Developer
0419/ 130	**Documentation of Current Medications in the Medical Record:** Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list **must** include ALL 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/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Iatrogenic Injury to Adjacent Organ/Structure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect	ACS
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Anastomotic Leak Intervention:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had an intervention (via return to operating room, interventional radiology, or interventional gastroenterology) for presence of leak of endoluminal contents (such as air, fluid, GI contents, or contrast material) through an anastomosis. The presence of an infection/abscess thought to be related to an anastomosis, even if the leak cannot be definitively identified as visualized during an operation, or by contrast extravasation would also be considered an anastomotic leak	ACS

N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Reoperation within the 30 Day Postoperative Period:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had any unplanned return to the operating room for a surgical procedure, for any reason, within 30 days of the principal operative procedure. The return to the OR may occur at any hospital or surgical facility (i.e. your hospital or at an outside hospital). Note: This definition is not meant to capture patients who go back to the operating room within 30 days for a follow-up procedure based on the pathology results from the principal operative procedure or concurrent procedure. Examples: Exclude breast biopsies which return for re-excisions; insertion of port-a-cath for chemotherapy	ACS
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Hospital Readmission within 30 Days of Principal Procedure:** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who a readmission (to the same or another hospital) for any reason, within 30 days of the principal procedure. The readmission has to be classified as an "inpatient" stay by the readmitting hospital, or reported by the patient/family as such	ACS
N/A/ N/A	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Surgical Site Infection (SSI):** (None provided by developer. Assumed description for specification provided. Requested Registry Reporting) Percentage of patients age 65 and older who had a surgical site infection	ACS
N/A/ N/A	**Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon:** Percentage of patients who underwent a non-emergency major surgery who had their risks of postoperative complications assessed by their surgical team prior to surgery using a data-based, patient-specific risk calculator and who received personal discussion of those risks. A higher value for this measure corresponds to higher quality	ACS

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We seek public comment on these proposals.

c. Proposed Reporting Mechanism Changes to PQRS Individual Measures for 2014 and Beyond

In addition to the measures and measures groups we are proposing to include or remove from the existing PQRS measure set, we propose to modify how existing PQRS measures can be reported. Specifically, we propose that the following measures would no longer be reportable through the claims-based reporting mechanism:

- PQRS #9 (NQF# 0105): Major Depressive Disorder (MDD): Antidepressant Medication during Acute Phase for Patients with MDD: Percentage of patients aged 18 years and older diagnosed with new episode of MDD and documented as treated with antidepressant medication during the entire 84-day (12-week) acute treatment phase. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient number of measures for these eligible professionals to report via claims.
- PQRS #64 (NQF# 0001): Asthma: Assessment of Asthma Control—Ambulatory Care Setting: Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated at least once for asthma control (comprising asthma impairment and asthma risk). *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This measure is contained within the asthma measures group.
- PQRS #53: Asthma: Pharmacologic Therapy for Persistent Asthma—Ambulatory Care Setting. *Rationale:* Changing PQRS measure #64 to a

registry only measure would affect this measure. There would be no way to use the MAV with this measure because it is part of the MAV cluster associated with PQRS #64.

- PQRS #65 (NQF# 0069): Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children aged 3 months through 18 years with a diagnosis of URI who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #66 (NQF# 0002): Appropriate Testing for Children with Pharyngitis: Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode. A higher rate represents better performance (that is, appropriate testing). *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #87 (NQF# 0398): Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 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 HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #89 (NQF# 0401): Hepatitis C: Counseling Regarding Risk of Alcohol Consumption: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #90 (NQF# 0394): Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy: Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic Hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims
- PQRS #116 (NQF# 0058): Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use: Percentage of adults aged 18 through 64 years with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #126: DM: Diabetic Foot and Ankle Care, Peripheral Neuropathy-Neurological Evaluation. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #127 (NQF# 0416): Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #176 (AQA Adopted): Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of 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:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #177 (AQA Adopted): Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease activity within 12 months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #178 (AQA Adopted): Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #179 (AQA Adopted): Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of RA who have an assessment and classification of disease prognosis at least once within 12 months. *Rationale:* 2012 claims data indicates that a low threshold of eligible professionals reported this measure. This proposal is also supported because there are still a sufficient amount of measures for these eligible professionals to report via claims.
- PQRS #148 (NQF# 0322): Back Pain: Initial Visit: 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:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.
- PQRS #149 (NQF# 0319): 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:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.

• PQRS #150 (NQF# 0314): Back Pain: Advice for Normal Activities: 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:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.

• PQRS #151 (NQF# 0313): Back Pain: Advice Against Bed Rest: 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:* We believe this measure (which is only reportable when reporting the entire Back Pain measures group) is more appropriately reported via registry.

d. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

Because we believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report, we previously proposed a new satisfactory reporting criterion in this section to provide group practices comprised of 25 or more eligible professionals the option to complete the CG CAHPS survey for purposes of satisfying the 2014 PQRS incentive and 2016 PQRS payment adjustment. Specifically, the survey measures that we propose to use for the PQRS program includes the following 12 summary survey measures:

• Getting timely care, appointments, and information;
• How well providers Communicate;
• Patient's Rating of Provider;
• Access to Specialists;
• Health Promotion & Education;
• Shared Decision Making;
• Health Status/Functional Status;
• Courteous and Helpful Office Staff;
• Care Coordination;
• Between Visit Communication;
• Helping Your to Take Medication as Directed; and
• Stewardship of Patient Resources.

The first seven measures proposed above are the same ones used in the Medicare Shared Savings Programs. As stated previously, we believe it is important to align measures across programs to the extent possible. The remaining five measures proposed above address arreas of high importance to Medicare and are areas where patient experience can inform the quality of care related to care coordination and efficiency. Please note that the group practice would bear the cost of having this survey administered. We seek public comment on these proposed measures.

11. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Participation in a Qualified Clinical Data Registry for 2014 and Beyond for Individual Eligible Professionals

For the measures for which eligible professionals participating in a qualified clinical data registry must report, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the American Tax Relief Act of 2012, provides that the Secretary shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a qualified clinical data registry. Section 1848(m)(3)(E) of the Act, as added by section 601(b) of the American Tax Relief Act of 2012, provides some flexibility with regard to the types of measures applicable to satisfactory participation in a qualified clinical data registry, by specifying that with respect to measures used by a qualified clinical data registry, 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. We propose to provide to qualified clinical data registries flexibility with regard to choosing the quality measures data available for individual eligible professionals to choose from to report to CMS using these qualified clinical data registries. We believe it is preferable for the qualified clinical data registries with flexibility in selecting measures since we believe these clinical data registries would know best what measures should be reported to achieve the goal of improving the quality of care furnished by their eligible professionals. Although we are proposing to allow these clinical data registries to determine the quality measures from which individual eligible professionals would choose to have reported to CMS, to ensure that CMS receives the same type of data that could be uniformly analyzed by CMS and sufficient measure data, we believe it is important to set parameters on the measures to be reported on and the types of measures should be reported to CMS. Therefore, we are proposing the following requirements for the measures that must be reported to CMS by a qualified clinical data registry for the purpose of its individual eligible professionals meeting the criteria for satisfactory participation under the PQRS:

• The qualified clinical data registry must have at least 9 measures, covering at least 3 of the 6 National Quality Strategy domains, available for reporting. The 6 National Quality Strategy domains are as follows:

++ *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 through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

++ *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

++ 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 in order to improve appropriate and timely patient and care team communication.

++ *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. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

++ *Efficiency and Cost Reduction.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

++ *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

• The qualified clinical data registry 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).

• The qualified clinical data registry may report on process measures, which are measures that focus on a process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome.

• The outcome and process measures reported must contain denominator data. That is, the lower portion of a fraction used to calculate a rate, proportion, or ratio. The denominator must describe the population eligible (or episodes of care) to be evaluated by the measure. This should indicate age, condition, setting, and timeframe (when applicable). For example, ''Patients aged 18 through 75 years with a diagnosis of diabetes.''

• The outcome and process measures reported must contain numerator data. That is, the upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator must detail the quality clinical action expected that satisfies the condition(s) and is the focus of the measurement for each patient, procedure, or other unit of measurement established by the denominator (that is, patients who received a particular service or providers that completed a specific outcome/process).

• The qualified clinical data registry must provide denominator exceptions for the measures, where approriate. That is, those conditions that should remove a patient, procedure or unit of measurement from the denominator of the performance rate only if the numerator criteria are not met. Denominator exceptions allow for adjustment of the calculated score for those providers with higher risk populations. Denominator exceptions allow for the exercise of clinical judgment and should be specifically defined where capturing the information in a structured manner fits the clinical workflow. Generic denominator exception reasons used in measures fall into three general categories: Medical, Patient, or System reasons.

• The qualified clinical data registry must provide denominator exclusions for the measures for which it will report to CMS, where appropriate. That is, those patients with conditions who should be removed from the measure population and denominator before determining if numerator criteria are met. (For example, Patients with bilateral lower extremity amputations would be listed as a denominator exclusion for a measure requiring foot exams.)

• The qualified clinical data registry must provide to CMS descriptions for the measures for which it will report to CMS by no later than March 31, 2014. 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.

We request comments on these proposals.

12. Proposals for PQRS Informal Review

Section 414.90(j) provides that eligible professionals and group practices may request an informal review of the determination that an eligible professional or group practice did not satisfactorily submit data on quality measures under the PQRS. Because we believe it is important to also allow eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry to be able to request an informal review of the determination that the eligible professional satisfactorily participated in a qualified clinical data registry, we are proposing to modify § 414.90(j) to allow individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review. We are not proposing to make any changes to the informal review process itself; rather, we propose to make the existing informal review process available to individual eligible professionals with regard to a determination that the individual eligible professional did not satisfactorily participate in a qualified clinical data registry.

We seek public comment on this proposal.

13. Plan for the Future of PQRS for the 2017 PQRS Payment Adjustment and Beyond

a. Future PQRS Reporting Periods

Under § 414.90(h)(1), the reporting period for the PQRS payment adjustment, for the payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied. When we first proposed the reporting periods for the PQRS payment adjustment, we received many comments from stakeholders who opposed basing the PQRS payment adjustment year on a reporting period occurring two years prior to the payment adjustment year (77 FR 69176). Stakeholders requested that CMS establish reporting periods occurring closer to the year in which the payment adjustment is applied. Although we understood the commenters' concerns, we stated it was not operationally feasible to create a full calendar year reporting period for the PQRS payment adjustment any later than two years prior to the adjustment year and still avoid retroactive payments or the reprocessing of claims. Although it is still operationally infeasible to establish a 12-month reporting period occurring any later than two years prior to the adjustment year for reporting via claims, we are seeking comment about this issue again. In particular, in future years, should CMS consider establishing a reporting period that occurs closer to the adjustment year for certain PQRS reporting mechanisms, such as the registry, EHR, and GPRO web interface reporting mechanisms? Also, should the reporting periods still be structured as 12-month reporting periods occurring in a calendar year or multiple years? What length of time should be used for the reporting period? For example, should the PQRS allow for shorter, quarterly reporting periods? We would consider such comments to the extent we address or revisit the reporting period for the PQRS payment adjustment in future rulemaking.

b. Plan for the Future of the PQRS GPRO

The PQRS GPRO has undergone significant changes since it was first introduced in 2010. Given stakeholder feedback with claims that constant changes to the GPRO has caused confusion for GPRO participants, we did not propose many changes to the GPRO for the 2014 PQRS incentive or 2016 PQRS payment adjustment. However, we continue to receive stakeholder feedback urging CMS to reconsider certain policies related to the GPRO, such as:

• *The definition of a PQRS group practice that limits the practice to a single TIN.* A group practice in PQRS is currently defined at § 414.90(b) as ''a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their billing rights to the TIN.'' Therefore, for group practices, CMS uses the TIN as the billing unit. Any PQRS incentive payments earned

are paid to the TIN holder of record. Stakeholders believe that limiting the definition of a group practice to ''a single TIN'' causes operational challenges to group practices that may operate as one healthcare entity but, due to business purposes, bill Medicare using multiple TINs.

This definition has become increasingly problematic particularly as some CMS programs with quality reporting components allow group practices containing multiple TINs to participate in these programs as a single group practice. We understand this concern. Therefore, we seek comment on whether we should modify the current definition of group practice to account for multiple TINs (that is, change the identification unit(s) to recognize a group practice). In addition, if we allow groups with multiple TINs to participate in PQRS as a single group practice, we seek comment on what parameters we should put in place. For example, if we allow multiple TINs to participate in PQRS as a single group practice, should we place geographical restrictions? Should we require that groups wishing to participate as a single group practice provide care for the same beneficiaries?

• *Self-Nomination/Registration Process.* We currently require group practices to self-nominate for each program year the group practices wish to participate in PQRS using the GPRO. Stakeholders have commented that annual self-nomination is duplicative, particularly when no changes to a group practice's composition have been made. We therefore seek comment as to whether, in future years, we should move away from requiring group practices to self-nominate/register for the GPRO each year. Once a group practice is approved to participate in PQRS as a GPRO, should we automatically assume that a group practice would participate in PQRS as a GPRO for future years until the group practice indicates otherwise?

• *Satisfactory Reporting Criterion for Group Practices Using the GPRO web interface.* Currently, if the pool of assigned beneficiaries for a group practice using the GPRO web interface is less than the specified reporting threshold (i.e., 411 assigned beneficiaries for group practices comprised of 100 or more eligible professionals), then the group practice is required to report on 100 percent of assigned beneficiaries for purposes of both the PQRS incentive and payment adjustment. Conceivably, a group practice could have as few as one beneficiary assigned to the group practice and still qualify for the PQRS incentive or avoid the PQRS payment adjustment as long as the group practice successfully reports the measures included in the web interface for that one beneficiary. As data collected from the GPRO web interface starts getting used to calculate performance benchmarks for the Value-based Payment Modifier and/or Physician Compare, we question whether performance results from group practices with few assigned beneficiaries could skew the benchmark calculations. We, therefore, invite comment on whether we should establish minimum reporting thresholds for group practices using the GPRO web interface as well as seek comment on what the appropriate thresholds should be. Or, should we consider requiring group practices to be in existence prior to the start of the reporting period to use the GPRO web interface?

c. Future of Use of the Claims-Based Reporting Mechanism in PQRS

According to the 2011 PQRS and eRx Experience Report, approximately 72 percent of eligible professionals (229,282 out of 320,422 eligible professionals) participating in PQRS in 2011 did so using the claims-based reporting mechanism. The claims-based reporting mechanism is the most widely used PQRS reporting mechanism. Unfortunately, the claims-based reporting mechanism is also the reporting mechanism that allows for the most errors in reporting. Unlike the registry and EHR-based reporting mechanisms, where the quality measures data is submitted at the end of the reporting period, eligible professionals must report quality measures data at the time they submit their claims for payment for services. Therefore, registry and EHR users are at an advantage as they are able to analyze their quality data at the end of the year for any changes that may need to be made due to follow up care. In addition, it is burdensome for CMS to analyze quality measures data from the claims-based reporting mechanism because it takes several months to analyze all claims for which reporting G-codes are submitted to CMS.

For these reasons, we seek comment as to whether CMS should eliminate the claims-based reporting mechanism beginning with the reporting period (calendar year 2017) for the 2019 PQRS payment adjustment.

d. Future Submission Timelines for the Registry, EHR, GPRO Web Interface and Qualified Clinical Data Registry Reporting Mechanisms

In the CY 2013 PFS final rule, we finalized the following deadlines for submitting quality measures data via claims, registry, EHR, and the GPRO web interface:

• For an eligible professional submitting PQRS quality measures data via claims, an eligible professional is required to submit no later than the last Friday of the second month after the end of the reporting period, that is, processed by February 28, 2014 for the reporting periods that end December 31, 2013 (77 FR 69178).

• For eligible professionals and group practices submitting quality measures data via registry and EHR, the registry or EHR is required to submit quality measures data no later than the last Friday of the February following the applicable reporting period (for example, February 28, 2014 for reporting periods occurring in 2013) (77 FR 69182).

• For group practices submitting quality measures data via the GPRO web interface, we stated we would provide group practices that are selected to participate in the GPRO using GPRO web interface reporting option with access to the GPRO web interface by no later than the first quarter of the year following the end of the reporting period under which the group practice intends to report (77 FR 69187). For example, for group practices selected for the GPRO for the 2013 incentive using the GPRO web interface tool, group practices selected to participate in the GPRO would be provided with access to the GPRO web interface by no later than the first quarter of 2014 for purposes of reporting for the applicable 2013 reporting period for the incentive.

We have received feedback from eligible professionals, group practices, and vendors that the submission deadlines come too soon after the close of the reporting period. Vendors, in particular, find it difficult to meet the submission deadlines in time to submit quality measures data on behalf of all their participating eligible professionals and group practices. While it is not technically feasible to allow for submission of quality measures data reported via claims any later than the last Friday of the second month after the end of the respective reporting period, we are exploring alternative deadlines for quality measures data that is submitted via registry, EHR, the GPRO web interface, and the newly proposed qualified clinical data registry.

Specifically, we are exploring ways to collect quality measures data on a quarterly basis, rather than allowing for submission of quality measures data only once following a respective reporting period. We seek public comment on allowing for quarterly submission of quality measures data as well as other alternatives that would allow CMS with the time necessary to perform quality measures data analysis prior to the assessment of PQRS payment adjustments.

e. Integration of Clinical Quality Measures Reported Under the Hospital Inpatient Quality Reporting (IQR) Program

We received feedback that, for certain hospital-based physicians who bill Medicare Part B services and therefore are able to participate in PQRS, the measures CMS has adopted under the PQRS do not adequately capture the nature of their practice. These physicians believe that measures such as those available in the Hospital IQR Program are more relevant to the quality of care these physicians provide. Therefore, under Section I.9, we proposed to include measures available under the Hospital IQR Program that have been retooled to be reported under the PQRS during the 12-month 2014 PQRS incentive and 12-month 2016 PQRS payment adjustment reporting periods via the registry-based reporting mechanism. We seek comment on whether additional Hospital IQR measures should be retooled for use in the PQRS in the same manner. In addition, we seek comment on whether CMS should attribute the reporting periods and performance results from the hospital IQR program to individual eligible professionals or group practices who elect to have their hospital's performance scores attributed to them.

f. Feedback Reports

For eligible professionals reporting PQRS quality measures data via claims, CMS provides each eligible professional who submits a valid reporting quality data code (QDC) two feedback reports each year that provides detailed information on an eligible professional's reporting performance. These feedback reports only provide data on PQRS reporting performance. Given our efforts to align with the Value-based Payment Modifier, we are exploring ways to merge the feedback reports provided to participants in the PQRS and Value-based Payment Modifier so that an eligible professional would receive one, merged feedback report showing reporting data for the PQRS and performance data for the Value-based Payment Modifier. We seek public comment on whether feedback reports for the PQRS and Value-based Payment Modifier should be merged.

I. 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 clinical quality measures (CQMs) for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

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 EHR Incentive Program Stage 2 Final Rule, we established clinical quality measure 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 this proposed rule, we are proposing 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.

1. Proposed Qualified Clinical Data Registry Reporting Option

Section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting'') requires the Secretary to develop a plan to integrate reporting on quality measures under the PQRS with reporting requirements related to meaningful use under the EHR Incentive Program. In response to section 1848(m)(7) of the Act, the PQRS and EHR Incentive Program have, in particular, taken steps to align their respective quality measures reporting criteria. For example, in the CY 2013 PFS final rule with comment period (77 FR 69190), the PQRS adopted criteria for satisfactory reporting for the 2014 PQRS incentive that aligns with the criteria for meeting the CQM component of achieving meaningful use under the Medicare EHR Incentive Program in 2014. Specifically, under the PQRS, an individual EP will meet the criteria for satisfactory reporting for the 2014 PQRS incentive using a direct EHR or EHR data submission vendor product that is CEHRT certified to the 2014 Edition certification criteria if, during the 12-month 2014 PQRS incentive reporting period, the EP reports 9 measures covering at least 3 National Quality Strategy 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 patient data (see Table 91, 77 FR 69194 through 69195).

As further described in section G of this proposed rule, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the American Taxpayer Relief Act of 2012, includes a provision that authorizes an additional standard for individual eligible professionals to meet the PQRS by satisfactorily participating in a qualified clinical data registry. In section G of this proposed rule, we proposed criteria for eligible professionals to satisfactorily participate in a qualified clinical data registry for the 2014 PQRS incentive.

For purposes of meeting the CQM reporting component of meaningful use for the Medicare EHR Incentive Program in 2014 and subsequent years, we propose to allow EPs to submit CQM information using qualified clinical data registries, according to the proposed definition and requirements for qualified clinical data registries discussed in section IV.I. of this proposed rule. We are proposing this new option under the Medicare EHR Incentive Program beginning with the reporting periods in 2014 for the following reasons: (1) To minimize duplicative reporting as directed under section 1848(o)(2)(B)(iii) of the Act for EPs who seek to participate in both the Medicare EHR Incentive Program and a qualified clinical data registry under the PQRS in 2014; (2) to further integrate reporting quality reporting options under the PQRS and the EHR Incentive Program as directed under section 1848(m)(7) of the Act; and (3) because the proposed criteria for the satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive are similar to criteria we finalized for meeting the CQM component of achieving meaningful use under the

Medicare EHR Incentive Program for 2014. In the event that the criteria established for satisfactory participation in a qualified clinical data registry under PQRS in the final rule are different from the proposed criteria, we intend to adopt the criteria that are finalized for PQRS to the extent feasible for the Medicare EHR Incentive Program. In addition to the criteria that are ultimately established for PQRS, we propose the following additional criteria that an EP who seeks to report CQMs for the Medicare EHR Incentive Program using a qualified clinical data registry must satisfy: (1) The EP must use CEHRT as required under the Medicare EHR Incentive Program; (2) the CQMs reported must be included in the Stage 2 final rule (see Table 8, 77 FR 54069) and use the same electronic specifications established for the EHR Incentive Program, (3) report 9 CQMs covering at least 3 domains, (4) if an EP's CEHRT does not contain patient data for at least 9 CQMs covering at least 3 domains, then the EP must report the CQMs for which there is patient data and report the remaining CQMs as ''zero denominators'' as displayed by the EP's CEHRT, and (5) an EP must have CEHRT that is certified to all of the certification criteria required for CQMs, including certification of the qualified clinical data registry itself for the functions it will fulfill (for example, calculation, electronic submission). We note that these proposed additional criteria are already final policies for the CQM reporting options that we established for EPs in the EHR Incentive Program Stage 2 final rule. We refer readers to that final rule for further explanation of the policies related to clinical quality measure reporting under the EHR Incentive Program (77 FR 54049–54089). The electronic specifications for the clinical quality measures can be found at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. We are proposing this qualified clinical data registry reporting option only for those EPs who are beyond their first year of demonstrating meaningful use (MU). For purposes of avoiding a payment adjustment under Medicare, EPs who are in their first year of demonstrating MU in the year immediately preceding a payment adjustment year must satisfy their CQM reporting requirements by October 1 of such preceding year (for example, by October 1, 2014 to avoid a payment adjustment in 2015). The proposed qualified clinical data registry reporting option would not enable an EP to meet the deadline to avoid a payment adjustment because these qualified clinical data registries would be submitting data on CQMs by the last day of February following the 2014 PQRS incentive reporting periods, which would occur after October 1, 2013. Therefore, EPs who are first-time meaningful EHR users must report CQMs via attestation as established in the EHR Incentive Program Stage 2 final rule (77 FR 54050). The reporting periods established in the EHR Incentive Program Stage 2 final rule would continue to apply to EPs who would choose to report CQMs under this proposed qualified clinical data registry reporting option for purposes of the Medicare EHR Incentive Program (77 FR 54049–54051). Please note that this may not satisfy requirements for other quality reporting programs that have established 12-month reporting periods, such as the PQRS.

Under section 1848(o)(2)(A)(iii) of the Act, EPs are required to use CEHRT to submit information on clinical quality measures for the EHR Incentive Program. The 2014 Edition certification criteria established by the Office of the National Coordinator for Health IT (ONC) set the requirements for certification that cover the functionality needed to ''capture and export'' (45 CFR 170.314(c)(1)), ''import and calculate'' (45 CFR 170.314(c)(2)), and for ''electronic submission'' (45 CFR 170.314(c)(3)) of each CQM that will be reported.

As EPs are required to use CEHRT under section 1848(o)(2)(A)(iii) of the Act, we propose that for the Medicare EHR Incentive Program, an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP's CEHRT. For example, if the registry would collect patient level data from EPs, calculate the CQMs, then submit to CMS the calculated results on behalf of the EP in either an aggregate level Quality Reporting Document Architecture (QRDA) Category III file or patient level QRDA–I files, then the registry would need to be certified for the CQM criteria listed at 45 CFR 170.314(c)(2) (''import and calculate'') for each CQM that will be submitted and 45 CFR 170.314(c)(3) (''electronic submission''). We note that EPs would still need to include a certified EHR Module as part of their CEHRT that is certified to the CQM criteria listed at 45 CFR 170.314(c)(1) (''capture and export'') for each of the CQMs that would be submitted to CMS for the purposes of meeting the CQM requirements of the Medicare EHR Incentive Program. If the qualified clinical data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry would need to be certified to the ''capture and export'' criteria listed at 45 CFR 170.314(c)(1). The certified EHR Module must be part of the EP's CEHRT.

We intend to revisit the certification criteria with ONC in the Stage 3 rulemaking for the purpose of developing a more flexible clinical data registry reporting option and certification criteria for the EHR Incentive Program when Stage 3 begins. We welcome public comment and recommendations on a more flexible clinical data registry reporting option for meeting the CQM reporting requirement for MU and on the certification criteria that ONC could incorporate for clinical data registries.

2. Proposed Group Reporting Option—Comprehensive Primary Care Initiative

The Comprehensive Primary Care (CPC) Initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, CMS 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 an enhanced payment to primary care practices that provide high-quality primary care. There are approximately 500 CPC participants 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*.

CPC practice sites will submit 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 (77 FR 54069–54075). In a continuing effort to align quality reporting programs and innovation initiatives, we propose to add a group reporting option for CQMs for the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a CPC practice site that successfully submits at least 9 electronically specified CQMs covering 3 domains. We propose that each of the EPs in the CPC practice site would satisfy the CQM reporting component of meaningful use for the relevant

reporting period if the CPC practice site successfully submits and meets the reporting requirements of the CPC Initiative. We propose that only those EPs who are beyond their first year of demonstrating meaningful use may use this proposed CPC group reporting option, for the reasons explained in the preceding section in regard to avoiding a payment adjustment under Medicare. We propose that EPs who successfully submit as part of a CPC practice site in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy their CQM reporting requirement for the Medicare EHR Incentive Program. The CPC practice sites must submit the CQM data in the form and manner required by the CPC Initiative.

If a CPC practice site fails the requirements established for the CPC Initiative, we note that the EPs who are part of the site would have the opportunity to report CQMs per the requirements established in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (77 FR 54049). We invite public comment on these proposals.

3. Reporting of Electronically Specified Clinical Quality Measures for the Medicare EHR Incentive Program

In the EHR Incentive Program Stage 2 final rule, we finalized the CQMs from which EPs would report beginning in CY 2014 under the EHR Incentive Program (77 FR 54069, Table 8). These CQMs are electronically specified and updated routinely to account for issues such as changes in billing and diagnosis codes and changes in medical practices. The requirements specified in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 allow for the reporting of different versions of the CQMs. However, it is not technically feasible for CMS to accept data that is reported according to the specifications of the older versions of the CQMs, including versions that may be allowed for reporting under the EHR Incentive Program. We stated in the EHR Incentive Program Stage 2 final rule that, consistent with section 1848(o)(2)(B)(ii) of the Act, in the event that the Secretary does not have the capacity to receive CQM data electronically, EPs may continue to report CQM data through attestation (77 FR 54076). Therefore, we propose 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 and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. For example, for the reporting periods in 2014, EPs who want to report CQM data electronically for purposes of satisfying the quality measure reporting component of meaningful use would be required to use the June 2013 version of the CQMs electronic specifications (available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*) and ensure that their CEHRT has been tested and certified to the June 2013 version of the CQMs for purposes of achieving the CQM component of meaningful use in 2014. EPs who do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) would be allowed to report CQM data to CMS by attestation for the Medicare EHR Incentive Program. For further explanation of reporting CQMs by attestation, we refer readers to the EHR Incentive Program Stage 1 final rule (77 FR 44430 through 44434) and the EHR Incentive Program's Registration and Attestation page (available at *https://ehrincentives.cms.gov/hitech/login.action*).

We invite public comment on these proposals. Specifically, we invite comment on whether there would be sufficient time for EHR technology developers to update their systems and timely distribute the updated CQM versions in a way that would enable EPs to report on the updated versions. Additionally, we invite comment on whether there are any data or logic dependencies in the eCQMs that EHR technology developers have experienced which, if not built in upfront and deployed before a reporting period, would result in inaccurate measures, if for example, an EHR technology was upgraded in the middle of an EP's reporting period to the newest version of the CQMs (if we finalized our proposal to only accept the lasted published specification of an CQM).

J. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has established a 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 healthcare costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare 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 **Federal Register** on November 2, 2011 (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

ACOs are required to completely and accurately report on all quality performance measures for all quality measurement reporting periods in each performance year of their agreement period. There are currently 33 quality performance measures under the Shared Savings Program. For Shared Savings Program ACOs beginning their agreement period in April or July, 2012, there will be two reporting periods in the first performance year, corresponding to calendar years 2012 and 2013. For ACOs beginning their agreement periods in 2013 or later, both the performance year and reporting period will correspond to the calendar year. Reporting on measures associated with a reporting period will generally be done in the spring of the following calendar year. For example, an ACO will submit quality measures for the 2015 reporting period in the spring of 2016.

1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment

Section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *'' and permits the Secretary to ''use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we incorporated certain Physician Quality Reporting System (PQRS) reporting requirements and incentive payments into the Shared Savings Program, including (1) The 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889 through 67890); (2) reporting via the GPRO web interface; (3) criteria for satisfactory reporting; and (4) set January 1 through December 31 as the reporting period. The regulation governing the incorporation of PQRS incentives and reporting requirements

under the Shared Savings Program is set forth at § 425.504.

Under section 1848(a)(8) of the Act, a payment adjustment will apply under the PQRS beginning in 2015 based on quality reporting during the applicable reporting period. Eligible professionals who are not satisfactory reporters will be subject to a payment adjustment applied to the PFS amount for covered professional services furnished by the eligible professional during 2015. For eligible professionals subject to the 2015 PQRS payment adjustment, the fee schedule amount is equal to 98.5 percent (and 98 percent for 2016 and each subsequent year) of the fee schedule amount that would otherwise apply to such services. To continue to align Shared Savings Program requirements with PQRS, for the 2013 reporting period (which will be used to determine the 2015 PQRS payment adjustment to PFS amounts), in the CY 2013 PFS final rule with comment (77 FR 69372), we amended § 425.504 to include the PQRS reporting requirements necessary for eligible professionals in an ACO to avoid the 2015 PQRS payment adjustment. Specifically, we required ACOs on behalf of eligible professionals that are ACO providers/suppliers to successfully report one ACO GPRO measure in 2013 to avoid the payment adjustment in 2015. We also provided that ACO providers/suppliers that are eligible professionals may only participate under their ACO participant TIN as a group practice under the PQRS GPRO for purposes of avoiding the payment adjustment in 2015. Thus, ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as an individual under the traditional PQRS or under the traditional PQRS GPRO under their ACO participant TIN. We note, however, that eligible professionals may bill Medicare under more than one TIN (for example, eligible professionals may bill Medicare under a non-ACO participant TIN in one practice location and also bill Medicare under the TIN of an ACO participant at another practice location). As a result, ACO provider/suppliers who are eligible professionals that bill under a non-ACO participant TIN during the year could participate under the traditional PQRS as either individual EPs or a group practice for purposes of avoiding the PQRS payment adjustment for the claims billed under the non-ACO participant TIN. In fact, such EPs would have to do so to avoid the PQRS payment adjustment with respect to those claims because the regulation at § 425.504 only applies to claims submitted by ACO providers/suppliers that are eligible professionals billing under an ACO participant TIN. If eligible professionals within an ACO meet the requirements for the PQRS payment adjustment established under the Shared Savings Program, only the claims billed through the TIN of the ACO participant will avoid the payment adjustment in 2015.

For the 2014 reporting period and subsequent reporting periods (which would apply to the PQRS payment adjustment for 2016 and subsequent payment years), we propose to align with the requirements for reporting under the traditional PQRS GPRO through the CMS web interface by amending § 425.504 to require that ACOs on behalf of their ACO providers/suppliers who are eligible professionals satisfactorily report the 22 ACO GPRO measures during the 2014 and subsequent reporting periods to avoid the downward PQRS payment adjustment for 2016 and subsequent payment years. Additionally, we propose to continue the current requirement that ACO providers/suppliers who are eligible professionals may only participate under their ACO participant TIN for purposes of the payment adjustment in 2016 and subsequent years.

We believe that the proposal to modify the requirements for ACOs to satisfactorily report the 22 ACO GPRO measures to avoid the 2016 payment adjustments would not increase burden on ACOs or on ACO providers/suppliers that are eligible professionals because ACOs must already report these measures in order to satisfy the Shared Savings Program quality performance standard. Thus, this proposal would not increase the total number of measures that must be reported by the ACO and its ACO providers/suppliers that are eligible professionals. We also note that these proposals would not affect the Shared Savings Program quality performance standard reporting requirement under which ACOs are currently required to report on 33 quality performance measures, which include all 22 of the ACO GPRO quality measures.

Additionally, ACOs are required to report certain measures using the GPRO web interface tool. Specifically, § 425.504(a)(1) and (b)(1) require that ACOs submit quality measures using the GPRO web interface to qualify on behalf of their eligible professionals for the PQRS incentive or to avoid the PQRS payment adjustment. This reporting mechanism is also referenced in § 425.308(e), which provides that quality measures that ACOs report using the GPRO web interface will be reported by CMS on Physician Compare.

Under § 414.90(h)(3)(i), group practices may report data under the traditional PQRS GPRO through a CMS web interface. The Shared Savings Program regulations 425.504(a)(1) and (b)(1) and § 425.308(e) specifically reference the use of the GPRO web interface for quality reporting purposes. We propose to amend these regulations to replace references to GPRO web interface with CMS web interface. We believe this change will ensure consistency with the reporting mechanism used under 414.90(h)(3)(i) and will also allow for the flexibility to use a similar web interface in the event that operational issues are encountered with the use of the GPRO web interface. We invite public comment on this proposal.

2. Medicare Shared Savings Program-Establishing the Quality Performance Benchmark

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 ''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.'' In the Shared Savings Program final rule, we finalized the following requirements with regard to establishing a performance benchmark for measures: (1) During the first performance year for an ACO, 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 each measure; (3) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures; and (4) contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national Medicare Advantage (MA) quality measure rates, or a national flat percentage. In the final rule, we indicated that we would not compare an ACO's quality performance to the performance of other ACOs for purposes of determining an ACO's overall quality score. We acknowledged, however, that in future program years, we should seek to incorporate actual ACO performance on quality measures into the quality benchmarks after seeking industry input through rulemaking.

a. Data Sources Used To Establish Performance Benchmarks

The regulation governing the data that CMS will use to establish the performance benchmarks for quality performance measures under the Shared Savings Program is set forth at § 425.502(b)(2). This provision states that CMS will define the performance benchmarks based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage. In the Shared Savings Program final rule, we responded to comments suggesting that quality performance benchmarks be set based on actual historical data submitted by ACOs. We stated that although we agreed that we should seek to incorporate actual ACO performance on quality scores into the quality benchmark, we would do so only in future rulemaking so that we could seek industry input. In addition, we noted that we expected to update the quality benchmarks over time, 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.

Consistent with our stated intention to incorporate actual ACO experience into quality measure benchmarks, for the 2014 reporting period, we propose to amend § 425.502(b)(2) to permit CMS to use all available and applicable national Medicare Advantage and Medicare FFS performance data to set the quality performance benchmarks. Specifically, in addition to using available national Medicare FFS rates, which include data reported through PQRS, and national MA quality measure rates, we propose to use data submitted by Shared Savings Program and Pioneer ACOs in 2013 for the 2012 reporting period to set the performance benchmarks for the 2014 reporting period. We propose to publish the quality benchmarks based upon these data prior to the beginning of the 2014 reporting period through subregulatory guidance. As stated in the Shared Savings Program final rule, we will establish benchmarks using the most currently available data source and the most recent available year of benchmark data prior to the start of the reporting period. In other words, data collected in 2014 from the 2013 reporting period would be used in conjunction with other available data to set benchmarks for the 2015 reporting period, and so on. We propose to retain the option of using flat percentages when data are unavailable, inadequate or unreliable to set quality performance benchmarks. Further, we clarify our intent to combine data derived from national Medicare Advantage and national Medicare FFS to set performance benchmarks when the measure specifications used under Medicare Advantage and FFS Medicare are the same. We propose to revise § 425.502(b)(2)(i) to reflect this clarification. We seek comment on these proposals, and whether there are other data sources that should be considered in setting performance benchmarks.

b. Ensuring Meaningful Differences in Performance Rates

Data collected by CMS from the GPRO and Physician Group Practice Demonstration participants in 2012 coupled with previous CMS experience indicates that using actual data to calculate quality performance may result in some measures' performance rates being tightly clustered. In this case, quality scores for the measure may not reflect clinically meaningful differences between the performance rates achieved by reporters of quality. For example, for some measures, the distribution of performance rates may have a spread of less than 2.0 percentage points between the 30th and 90th percentiles. In such an instance, even though there is little distinction in actual performance rates, a slight difference in performance on the measure may result in a significant difference in the number of quality points obtained for the Shared Savings Program. For example, two separate ACOs at the 50th percentile and the 90th percentile may have only a few tenths of a percentage point difference in their actual performance, but under the Shared Savings Program scoring methodology, the difference between their quality scores for that measure would be more noteworthy (1.4 points versus 2.0 points).

We continue to believe it is desirable to use performance rates for measures based on actual data because doing this creates benchmarks that are simple to understand and apply, even if the rates are clustered, as the data reflect achievable performance on quality measures. However, allowing clustered performance rates for a measure may result in payment differences that are not be associated with clinically meaningful differences in patient care, as noted in the example above.

Keeping these issues in mind, we propose to develop a methodology to spread clustered performance on measures. The first step in developing that methodology is to identify when performance on a measure is clustered. Clustering could be defined as less than a certain spread between performance rates in an identified range, for example, less than 6.0 percentage points between the performance rates associated with the 30th and 90th percentiles, or less than 10.0 percentage points between the minimum and maximum values achieved by previous reporters of the quality measure. Alternatively, clustering could be defined as a spread of performance rates of less than x percentage points between any two deciles, for example, less than a 1.0 percentage point difference between the 60th and 70th decile.

Once a clustered measure has been identified, the next step is to apply a methodology to spread or separate the performance rates within the measure. It is important to establish a meaningful performance rate, or starting point, around which to differentiate or spread the performance. For example, selecting a certain percentile or median value may represent one option for establishing a reasonable starting point. Once the starting point is set, then we could implement a series of fixed percentage point intervals around the starting point in both a positive and negative direction to increase the spread, for example, applying a fixed 1.0 percentage point interval between scored deciles. For example, if the starting point is the 60th percentile, and the performance rates at the 60th and 70th percentiles were observed to be 77.15 and 77.65 respectively, there would be only a 0.5 spread between the deciles. In contrast, applying a fixed 1.0 percentage point interval to increase spread would result in a 1.0 difference between these rates, and the new performance rates would be 77.15 and 78.15 at the 60th and 70th percentiles, respectively. In the alternative, we could take the spread calculated from a subset (for example, ACO performance only) of the underlying performance data if we believe that data reported by ACOs show a different variability than other data sources. For example, the spread between the measure's percentiles could be based on historical ACO distribution only, not the historical distribution of Medicare Advantage and/or national fee-for-service, PQRS, and ACO data. The historical ACO distribution could then be applied to the Medicare Advantage and/or national fee-for-service, PQRS, and ACO percentile distribution to establish the measure's percentiles.

We believe that a clinically meaningful assessment of ACO quality is important. We also are interested in providing a pathway for ACOs new to quality reporting to achieve the quality reporting standard, and an incentive for

experienced ACOs to continue improving and performing at high levels. We are therefore proposing to use a standardized method for calculating benchmark rates when a measure's performance rates are tightly clustered. We propose that the application of a methodology to reduce measure clustering would only apply to quality measures whose performance rates are calculated as percentiles, that is, the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe that measures whose performance rates are calculated as ratios already demonstrate a high degree of clinically meaningful differences because they are risk adjusted to reflect the health status of the patient population being measured.

We propose to define a tightly clustered measure, including clinical process and outcome measures reported through the GPRO web interface and CAHPS measures, as one that demonstrates less than a 6.0 percentage point spread in performance rates between the 30th and 90th percentiles. We believe using the 30th and 90th percentiles as the lower and upper bounds is reasonable because these bounds have been given some significance in earlier rulemaking; specifically, the Shared Savings Program rule sets the ACO's minimum attainment level at the 30th percentile, below which the ACO achieves no points, and the ACO achieves full points for quality reporting at or above the 90th percentile. Further, we propose to establish the starting point at the 60th percentile, the midpoint between the 30th and 90th percentiles, and then apply a positive 1.0 fixed percentage point interval for each decile above the 60th percentile and a negative 1.0 fixed percentage point interval for each decile below the 60th percentile.

We recognize that spreading tightly clustered performance measures would decrease the lower bound necessary to meet the minimum attainment level for the measure, giving ACOs new to quality reporting a greater opportunity to meet the quality performance standard. At the same time, spreading tightly clustered performance rates would increase the upper bound necessary for achieving the maximum available quality points for the measure, giving already experienced ACOs an incentive to continue improving quality. Applying a 1.0 fixed percentage point interval achieves the goal of creating meaningful differences in performance. Further, we believe that applying a 1.0 fixed percentage point interval represents a tempered and reasonable interval that does not spread performance rates to levels that are too easy to achieve on the lower bound or too difficult to achieve on the upper bound.

For example, Table 57 demonstrates the original spread of a quality measure, based on all available data, which is compressed from a range of 75.83 at the 30th percentile to 79.23 at the 90th percentile, that is, a spread of less than 6.0 percentage points. When the proposed methodology is applied, the 60th percentile (or 77.15 percent), serving as the starting point, remains unchanged. The spread increases 6.0 percentage points from 74.15 at the 30th percentile to 80.15 at the 90th percentile. As demonstrated and explained above, this methodology improves the distinction in performance between the minimum attainment level (30th percentile) and the maximum attainment level (90th percentile).

TABLE 57—PROPOSED METHODOLOGY TO REDUCE CLUSTERED PERFORMANCE RATES

Percentile	30th	40th	50th	60th	70th	80th	90th
Original performance rates using all available data	75.83	76.21	76.76	77.15	77.65	78.21	79.23
Performance rates using methodology to reduce clustering	74.15	75.15	76.15	77.15	78.15	79.15	80.15

*Example is for illustration purposes only and is not based on actual data.

We propose to amend § 425.502(b) to reflect this methodology to reduce clustering. We are seeking comment on these proposals. Specifically, we are seeking comment on whether or not a methodology should be applied to spread out clustered performance on measures. We are also seeking comment on the proposal to define clustered performance on a measure as one in which the spread of performance rates between the 30th and 90th percentiles is less than 6.0 percentage points, or whether other values should be used to define clustered measure performance, for example, when the minimum and maximum reported values are spread by less than 10.0 percentage points. We are seeking comment on whether there are alternative methodologies that should be considered to spread out clustered performance on measures. In addition, we are seeking comment on whether measures that are calculated as ratios should be excluded from this methodology. We are also seeking comment on whether all available relevant data should be considered when developing the spread between measures, or whether only the relevant performance data from a subset of reporters, such as ACO-reported data, as discussed above, should be used to determine the appropriate spread between deciles.

c. Scoring CAHPS Measures Within the Patient Experience of Care Domain

The preamble to the Shared Savings Program final rule (76 FR 67895–67900) outlines the total potential points available per domain as demonstrated in Table 58. As indicated in Table 58, under the final rule the Patient/Caregiver Experience Domain is weighted equally with other three quality domains at 25 percent and consists of 2 measures: a composite of six Clinician and Group (CG) CAHPS summary survey measures (1) Getting Timely Care, Appointments and Information, (2) How Well Your Doctors Communicate, (3) Patient's Rating of Doctor, (4) Access to Specialists, (5) Health Promotion and Education, (6) Shared Decision Making) and a Health Status/Functional Status measure. The six measures included in the composite will transition to pay-for-performance starting in the second year of an ACO's agreement period. In contrast, the Health Status/Functional Status measure will remain pay-for-reporting throughout the ACO's entire agreement period.

TABLE 58—TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (percent)
Patient/Caregiver Experience	7	1 measure, with 6 survey module measures combined, plus 1 individual measure.	4	25
Care Coordination/ Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points) ..	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	23	48	100

*From Table 4 in the Shared Savings Program Final Rule (76 FR 67899).

The result of this point system is that performance on the six patient experience measures is worth only 12.5 percent of an ACO's total performance score because the other 12.5 percent of the Patient/Caregiver Experience domain is the Health Status/Functional Status measure, which is a pay-for-reporting measure for all program years. However, we believe that each of these seven measures is equally important within the Patient/Caregiver Experience domain, and that scoring within the domain should better reflect performance on these measures, thereby placing a greater emphasis on the voice of the patient through patient-reported outcomes and experiences. We believe that increasing the weight of the 6 measures that will become pay-for-performance in the second year of the agreement period will incentivize ACOs to improve their performance on these measures. A policy to place a greater emphasis on patient-reported outcomes and experiences is consistent with our goal to improve the quality of care furnished by ACOs over time.

Therefore, we are proposing to modify the point scoring for the Patient/Caregiver Experience domain as demonstrated in Table 59. As modified, each of the 7 survey module measures within the domain would be assigned a maximum value of 2 points. The Patient/Caregiver Experience domain would then be worth a total of 14 points, rather than 4 points. The end result would be that each of the 7 measure modules in the domain would have equal weight. We note that this change would not affect the weighting of the domain itself in relationship to the other three domains; it would remain 25 percent of the ACO's total quality performance score.

TABLE 59—MODIFIED TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (percent)
Patient/Caregiver Experience	7	7 individual survey module measures	14	25
Care Coordination/Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points) ..	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	28	58	100

We believe that giving equal weight to each of the Patient/Caregiver Experience measures modules is appropriate because it places greater emphasis on patient-reported experiences, promotes clinically meaningful differences in ACO performance within the domain, and is consistent with the statutory mandate to improve quality of care furnished by ACOs over time. The proposed change would also bring the total points for the domain in line with the points available in other domains.

We seek comment on our proposal to modify the point scoring within the Patient/Caregiver Experience domain.

K. 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 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 value-based payment modifier to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the value-based payment modifier to be budget neutral.

In this proposed rule, we continue to phase in implementation of the value-based payment modifier by applying it to small groups of physicians and by increasing the amount of payment at risk. We also propose to refine the methodologies used in our approach to calculating the value-based payment modifier in order to better identify both high and low performers for upward and downward payment adjustments.

2. Governing Principles for Physician Value-Based Payment Modifier Implementation

In the CY 2013 PFS final rule with comment period (77 FR 69306), we

stated that the value-based payment modifier has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and more effective healthcare by providing upward payment adjustments under the PFS to high performing physicians (and groups of physicians) and downward adjustments for low performing physicians (and groups of physicians). We also noted that Medicare is implementing value-based payment adjustments for other types of services, including inpatient hospital services. Further, in implementing value-based purchasing initiatives generally, we seek to recognize and reward high quality care and quality improvements, and to promote more efficient and effective care through the use of evidence-based measures, the reduction in administrative burden and duplication, and less fragmented care.

In the CY 2013 PFS final rule with comment period, we established that the following specific principles should govern the implementation of the value-based payment modifier (77 FR 69307).

- *A focus on measurement and alignment.* Measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups, reflect the diversity of services furnished, and be consistent with the National Quality Strategy and other CMS quality initiatives, including the PQRS, the Medicare Shared Savings Program, and the Medicare EHR Incentive Program.
- *A focus on physician choice.* Physicians should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting physicians' 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 value-based payment modifier 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.
- *A focus on actionable information.* The Physician Feedback reports should provide meaningful and actionable information to help groups of physicians and physicians identify clinical areas where they are doing well, as well as areas in which performance could be improved by providing groups of physicians with feedback reports on the quality and cost of care they furnish to their patients.
- *A focus on a gradual implementation.* The value-based payment modifier should focus initially on identifying high and low performing groups of physicians. Moreover, groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in CY 2015. 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 Value-Based Payment Modifier

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the value-based payment modifier 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). For purposes of establishing group size only, we use the definition of an eligible professional as specified in section 1848(k) of the Act. We apply the value-based payment modifier to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing is not affected. We apply the value-based payment modifier to the items and services billed by physicians under the TIN, not to other eligible professionals that also may bill under the TIN. We identify groups of physicians subject to the value-based payment modifier for CY 2015 based on a query of Medicare's Provider Enrollment, Chain, and Ownership System (PECOS) on October 15, 2013, and we remove any groups from this list if, based on a claims analysis, the group of physicians did not have 100 or more eligible professionals that submitted claims during the performance period (77 FR 69310).

We established CY 2013 as the performance period for the value-based payment modifier that will be applied to payments during CY 2015 and CY 2014 as the performance period for the value-based payment modifier that will be applied to payments in CY 2016 (77 FR 69314). We also finalized that we will not apply the value-based payment modifier 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 initiatives (77 FR 69313). From an operational perspective, we will apply this policy to any group of physicians in which one or more physician(s) participate(s) in one of these programs or initiatives during performance periods CY 2013 or CY 2014.

We finalized policies to determine the amount of the value-based payment modifier 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 value-based payment modifier for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. For groups that make this election, we use the performance rates on the quality measures reported through the PQRS reporting mechanism that the group selects for 2013 (that is, group practice reporting option (GPRO) web-interface, CMS-qualified registry, or PQRS Administrative Claims option) and the performance rates on three outcome measures to calculate the group's quality composite under the quality-tiering approach. If a group in Category 1 that elects quality-tiering self-nominates for the GPRO web-interface or CMS-qualified registry and does not meet the satisfactory reporting criteria for the PQRS incentive payment, we use the group's performance on the Administrative Claims option to calculate the group's quality composite under the quality-tiering approach. The value-based payment modifier 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 value-based payment modifier 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 value-based payment modifier for the CY 2015 payment adjustment period is -1.0 percent.

We also finalized the following policies to calculate the value-based payment modifier using the quality-tiering approach. The quality-tiering approach requires creation of quality and cost composites for each group of physicians subject to the value-based payment modifier. The following brief summary describes the policies adopted in last year's final rule with comment

period (77 FR 69320 through 69326). To create the quality composite, we create a standardized score for each quality measure reported through the group's selected PQRS reporting mechanism, as well as the group's performance on three outcome measures (two composite measures of potentially preventable hospital admissions for acute and chronic conditions and a measure of all-cause hospital readmissions). The standardized score for each quality measure is calculated by dividing the difference between the group's performance rate and the measure's benchmark (the national mean of the measure's performance rate from the previous year) by the measure's standard deviation. The standardized scores for each measure are classified into one of six domains based on the national priorities related to clinical care, patient experience, population/community health, patient safety, care coordination, and efficiency established in the National Quality Strategy. Within each domain, we weight each measure's standardized score equally to arrive at a domain score. The domains are then equally weighted to form a quality of care composite. When a domain does not contain quality measures (for example, when a group chooses a reporting mechanism that does not contain measures in the domain), the remaining domains would be equally weighted to form the quality of care composite.

Additionally, we finalized a policy to construct the cost composite using five measures of total per capita costs for beneficiaries attributed to the group practice. The five measures are total per capita costs (both Parts A and B) and total per capita costs for beneficiaries with four specific chronic conditions: chronic obstructive pulmonary disease (COPD), heart failure, coronary artery disease (CAD), and diabetes. We attribute beneficiaries to each group using a two-step process that examines whether the group furnished the plurality (that is, more than any other group) of primary care services to the beneficiary. This attribution methodology is similar to the attribution rule we use for the Medicare Shared Savings Program and the PQRS GPRO web interface. We create a standardized score for each measure by dividing the difference between the group's performance rate and the measure's benchmark (the national mean of the measure's performance rate for the performance period) by the measure's standard deviation. We then classify each measure's standardized score into one of two domains: total per capita costs for all attributed beneficiaries (one measure) and total per capita costs for all attributed beneficiaries with specific conditions (four measures). Within each cost domain, each measure is equally weighted. In those instances in which we cannot calculate a particular cost measure because, for example, the number of cases is fewer than 20, we will weight the remaining cost measures in the domain equally. Similar to the quality of care composite, each cost domain is weighted equally to form the cost composite, unless one of the domains contains no measures, in which case the remaining domain will be weighted at 100 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 one or more standard deviations above or below the mean. We compare the group's quality of care composite classification with the cost composite classification to determine the value-based payment modifier adjustment for the CY 2015 payment adjustment period according to the amounts in Table 60.

TABLE 60—2015 VALUE MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost
High quality	+2.0x*	+1.0x*	+0.0%
Average quality	+1.0x*	+0.0%	-0.5%
Low quality	+0.0%	-0.5%	-1.0%

*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 60 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 value-based payment modifier that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (×). These calculations will be done after the performance period has ended. Accordingly, because the performance period for the CY 2015 value-based payment modifier is CY 2013, these calculations will be performed after December 31, 2013.

This scoring methodology also provides an additional upward payment adjustment of +1.0x to groups of physicians that care for high-risk patients (as evidenced by the average HCC risk score of the attributed beneficiary population) and submit data on PQRS quality measures through PQRS via the GPRO using the web-interface or CMS-qualified registry. We will increase the upward payment adjustment from +2.0x to +3.0x for groups of physicians classified as high quality/low cost and from +1.0x to +2.0x for groups of physicians that are either high quality/average cost or average quality/low cost if the group of physicians' attributed beneficiary population has an average risk score that is in the top 25 percent of the distribution of beneficiary risk scores nationwide. This additional upward payment adjustment (+1.0x for the CY 2015 payment adjustment period) will not apply to groups of physicians that select the PQRS Administrative Claims reporting mechanism. Finally, we provide an informal review process to enable a group of physicians to inquire about the calculation of its value-based payment modifier.

Since adopting these policies, the Institute of Medicine released a new report, ''Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care: Preliminary Committee Observations,'' observing that to improve value, ''payment reforms need to create incentives to encourage behavioral change at the locus of care (providers and patient).'' [2] Our approach to implementing the value-based payment modifier is consistent with this vision because it ties a group practice's payment to its

[2] Institute of Medicine, ''Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Health Care: Preliminary Committee Observations,'' (2013), p.29.

actions by rewarding high performing groups of physicians and penalizing low-performing groups of physicians.

On January 31, 2013, we submitted two cost measures—the total per capita costs for all attributed beneficiaries measure and the Medicare Spending per Beneficiary measure—to the National Quality Forum for endorsement. We have gained valuable feedback on a variety of issues (for example, attribution and risk adjustment) as we work with the National Quality Forum on the endorsement process for our cost measures. CMS is committed to refining our cost measures through future rulemaking based on feedback we receive from NQF and other stakeholders.

As discussed below in section K.5, we provided 2011 Quality and Resource Use Reports (QRURs) to 54 large group practices and to over 31,000 individual physicians in nine states that practice in group of physicians with 25 or more eligible professionals. These reports contained performance information on the quality of care furnished, and the cost of that care, to Medicare beneficiaries by these physicians and groups of physicians. Overall findings and results from these reports confirm that we can develop reliable and valid quality and cost measures at the group and individual physician level on which to base the value-based payment modifier. Moreover, group report recipients have found the reports informative and they have suggested ways to improve them to facilitate care coordination and quality improvement. We have adopted many of these suggestions in the QRUR reports that we plan to make available later this year.

4. Provisions of This Proposed Rule

In this proposed rule, we propose additions and refinements to the existing value-based payment modifier policies. These proposals continue our phased-in implementation of the value-based payment modifier by reinforcing our emphasis on quality measurement, alignment with the PQRS, physician choice, and shared accountability. Specifically, this proposed rule includes the following proposals:

- To apply the value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016.
- To make quality-tiering mandatory for groups within Category 1 for the CY 2016 value-based payment modifier, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology, and groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments determined under the quality-tiering methodology.
- To increase the amount of payment at risk under the value-based payment modifier from 1.0 percent to 2.0 percent in CY 2016.
- To align the quality measures and quality reporting mechanisms for the value-based payment modifier with those available to groups of physicians under the PQRS during the CY 2014 performance period.
- To include the Medicare Spending Per Beneficiary (MSPB) measure in the total per capita costs for all attributed beneficiaries domain of the cost composite.
- To refine the cost measure benchmarking methodology to account for the specialties of the physicians in the group.

a. Group Size

In the CY 2013 PFS final rule with comment period, we stated that we would gradually phase in the value-based payment modifier 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. We noted our view that it would be reasonable to focus on groups with 100 or more eligible professionals before expanding the application of the value-based payment modifier to more groups and solo practitioners in CY 2016 and beyond.

To continue our phase-in of the value-based payment modifier, we believe it is appropriate to lower the group size threshold for CY 2016 payment adjustments, which will be based on performance during CY 2014. Table 61 shows the number of groups, eligible professionals (EPs) and physicians in groups of various sizes based on an analysis of calendar year 2011 claims with a 90-day run-out period. We note that the number of EPs includes other practitioners, such as physician assistants and nurse practitioners, in addition to physicians.

TABLE 61—ELIGIBLE PROFESSIONAL/PHYSICIAN GROUP SIZE DISTRIBUTION

[2011 claims]

Group size	Number of groups (TINs)	Eligible professionals	Number of physicians	Percent of physicians	Cumulative percentage
100+ EPs	1,132	311,094	215,936	25.7	25.7
50–99EPs	1,622	110,862	76,318	9.1	34.8
25–49 EPs	3,729	126,596	88,065	10.5	45.3
20–24 EPs	1,890	41,334	28,756	3.4	48.7
10–19 EPs	8,653	116,379	81,829	9.7	58.4
2–9 EPs	68,702	241,732	174.758	20.8	79.2
1 EP	222,097	222,097	175,115	20.8	100.0
Total	307,825	1,170,094	840,777	100	

We propose to apply the value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals. We estimate that this proposal would cause approximately 17,000 groups (TINs) and nearly 60 percent of physicians to be affected by the value-based payment modifier in CY 2016. We believe this proposal continues our policy to phase in the value-based payment modifier by ensuring that the majority of physicians are covered in CY 2016 before it applies to all physicians in CY 2017. As discussed below in Section K.5, CMS conducted statistical reliability analyses on the PQRS quality measures and the cost measures contained in the 2010 and 2011 groups and individual Quality and Resource Use Reports (QRURs). These reports contained the same PQRS quality measures and cost measures that we will use for the value-based payment modifier. Both the quality and cost measures in the group reports were statistically reliable at a high level. Moreover, the average reliability score

was high for 98 percent of the individually reported PQRS measures and all of the cost measures (with a case size of at least 20) included in the individual feedback reports. Given these results, we believe that we can reliably apply a value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016 and to smaller groups and to solo practitioners in future years. Accordingly, we propose to revise the regulations at § 414.1210 to reflect that the CY 2016 value-based payment modifier would be applicable to physicians that are in groups with ten or more eligible professionals. We seek comments on this proposal.

We propose to identify groups of physicians that would be subject to the value-based payment modifier (for example, for CY 2016, groups of physicians with 10 or more eligible professionals) using the same procedures that we finalized in the CY 2013 PFS final rule with comment period (for a description of those procedures, we refer readers to 77 FR 69309 through 69310). Rather than querying Medicare's PECOS data base as of October 15 or another date certain, however, we propose to perform the query within 10 days of the close of the PQRS group self-nomination/registration process during the relevant performance period year. For example, for the CY 2016 value-based payment modifier, within 10 days of the close of the PQRS group self-nomination/registration process that will occur during the fall of CY 2014. We propose to revise the regulations at § 414.1210(c) to reflect that identification of the groups of physicians subject to the value-based payment modifier is based on a query of PECOS at the close of the PQRS registration period and that groups of physicians are removed from this list if, based on a claims analysis, the group of physicians 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. We seek comment on this proposal.

b. Approach to Setting the Value-Based Payment Modifier Adjustment Based on PQRS Participation

In the CY 2013 PFS final rule with comment period (77 FR 69311), we adopted a policy to categorize groups of physicians subject to the value-based payment modifier in CY 2015 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2015 value-based payment modifier into two categories. Category 1 includes groups 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 for CY 2013. Groups of physicians in Category 1 may elect to have their value-based payment modifier for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. The value-based payment modifier for groups of physicians in Category 1 that do not elect quality tiering is 0.0 percent, meaning that physicians in these groups will not receive a payment adjustment under the value-based payment modifier for CY 2015. Category 2 includes groups of physicians that do not fall within Category 1. For those groups of physicians in Category 2, the value-based payment modifier for CY 2015 is −1.0 percent.

We propose to use a similar two-category approach for the CY 2016 value-based payment modifier based on a group of physicians' participation in the PQRS but with different criteria for inclusion in Category 1. Category 2 would include those groups of physicians that are subject to the CY 2016 value-based payment modifier and do not fall within Category 1. Our proposal is intended to accommodate the various ways in which physicians can participate in the PQRS in CY 2014—either as a group practice participating in the PQRS GPRO or individually. We established in the CY 2013 PFS final rule with comment period that groups of physicians that wish to participate as a group in the PQRS during CY 2014 must self-nominate and select one of three PQRS GPRO reporting mechanisms: GPRO web interface, qualified registry, or EHR (77 FR 69199 through 69200 (Table 93)). We also established the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2016 (77 FR 69200 through 69202) and we have proposed to modify these criteria as described in Table 27 of this proposed rule. In order to maintain alignment with the PQRS, for purposes of the CY 2016 value-based payment modifier, we propose that Category 1 would include those groups of physicians that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHRs, or qualified registry reporting mechanisms) for the CY 2016 PQRS payment adjustment.

We understand that not all groups of physicians may want to participate in PQRS as a group under the GPRO in CY 2014. These groups of physicians may prefer to have all of their eligible professionals continue to report PQRS measures as individuals so that physicians and other eligible professionals in the group are able to report data on quality measures that reflect their own clinical practice. For example, a thoracic surgeon in a multi-specialty group practice may wish to report data on different quality measures than those on which a dermatologist or urologist in the same group practice may wish to report data. In addition, eligible professionals in these groups of physicians may wish to use different reporting mechanisms to report data for PQRS, such as the claims-based reporting mechanism, EHRs, qualified registries, or the proposed qualified clinical data registry reporting mechanism. Therefore, for the CY 2016 value-based payment modifier, we propose to include in Category 1 groups of physicians that do not self-nominate to participate in the PQRS as a group practice in CY 2014 and that have at least 70 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. The criteria for satisfactory reporting by individual eligible professionals for the claims, qualified registry, and EHR reporting mechanisms for the CY 2016 PQRS payment adjustment were established in the CY 2013 PFS final rule with comment period (77 FR 69194 through 69195 (Table 91), 69200–69202). We are proposing in Table 25 of this proposed rule the criteria for satisfactory participation in a qualified clinical data registry and other proposed changes to the criteria for satisfactory reporting for the CY 2016 PQRS payment adjustment. Another way to state this proposal is that a group of physicians subject to the CY 2016 value-based payment modifier would be in Category 1 if at least 70 percent of the individual eligible professionals in the group avoid the CY 2016 PQRS payment adjustment by any of the reporting options available under the PQRS.

We are proposing a 70 percent threshold for three reasons. First, although we expect 100 percent of a group's eligible professionals to participate in PQRS, we believe that we will obtain a reliable indicator of the

group's quality if at least 70 percent of the eligible professionals in the group meet the criteria to avoid the PQRS payment adjustment. We recognize that many individual eligible professionals may be reporting data on PQRS measures for the first time in CY 2014 and we do not seek to impose too high a burden on these groups that does not increase the reliability of the group's quality performance data for purposes of the value-based payment modifier. Second, the vast majority of eligible professionals participate in the PQRS as individuals, not as members of a group practice. Third, based on an examination of 2011 PQRS data, at least 63 percent of groups of physicians (TINs) participating in the PQRS with fewer than 50 eligible professionals would meet the 70 percent threshold already. At a 70 percent threshold, however, only 29 percent of groups of physicians participating in the PQRS of more than 100 eligible professionals have at least 70 percent of their eligible professionals meeting the criteria for satisfactory reporting in 2011. We believe that this result is consistent with our policy to encourage group reporting by the very largest groups of physicians. Indeed, these large groups have several reporting mechanisms available under the PQRS GPRO including the web interface, registries, and EHRs. Accordingly, we also propose to revise the regulation text at § 414.1225, which was previously specific to the CY 2013 performance period and only referred to quality measures reported by groups of physicians rather than individual eligible professionals within a group. We seek comment on these proposals.

For a group of physicians that would be subject to the CY 2016 value-based payment modifier to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of the 70 percent option described above) would need to be met during the CY 2014 performance period for the PQRS CY 2016 payment adjustment. We note that any reporting periods that are established under the PQRS would continue to apply for purposes of the PQRS. In the event that the criteria that are finalized for the CY 2016 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 2016 PQRS payment adjustment.

We propose to more fully phase-in the quality-tiering methodology for calculating the value-based payment modifier for CY 2016 based on the number of eligible professionals in the group. We propose that groups in Category 1 would no longer have the option to elect quality tiering for the CY 2016 value-based payment modifier (as was the case for the CY 2015 value-based payment modifier) and instead would be subject to mandatory quality tiering. We propose to apply the quality-tiering methodology to all groups in Category 1 for the value-based payment modifier for CY 2016, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, we propose 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 value-based payment modifier. We believe this proposed approach would reward groups of physicians that provide high-quality/low-cost care, reduce program complexity, and more fully engage groups of physicians in our plans to implement the value-based payment modifier. Accordingly, we propose to revise the regulations at § 414.1270 to reflect the proposal to make the quality-tiering methodology mandatory, with the exception noted above, for all groups of physicians subject to the value-based payment modifier in CY 2016 that fall within Category 1. We seek comment on this proposal. We are also revising the regulations at § 414.1270 to clarify that for the CY 2015 payment adjustment period a group may be determined under the quality-tiering methodology to have poor performance based on low quality and high costs, low quality and average costs, or average quality and high costs.

For groups of physicians with 100 or more eligible professionals, we believe it is appropriate to begin to phase in both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2016 value-based payment modifier. Based on 2011 claims, we estimate that there are approximately 1,100 groups of 100 or more eligible professionals. We believe that such large groups should already be focused on quality improvement and that they have ample ability to do so. These groups should have developed the internal means to track and improve the quality of care they furnish to Medicare FFS beneficiaries. For example, several large group practices that have participated in the PQRS GPRO have redesigned their electronic medical records systems to capture data to continually monitor their performance on those quality measures and provide alerts at the point of care to physicians and practitioners to further facilitate provision of high quality care to Medicare beneficiaries. Moreover under the quality-tiering methodology for calculating the value-based payment modifier as we established in the CY 2013 PFS final rule with comment period and have updated in this proposed rule, groups of physicians that furnish high quality care will not have a downward adjustment, even if they furnish such care at high costs. Thus, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups of physicians with 100 or more eligible professionals in 2016. We seek comments on our proposals and, in the alternative, whether we should treat groups of physicians with 100 or more eligible professionals in the same manner as we propose to treat groups of physicians with between 10 and 99 eligible professionals under the quality-tiering methodology as described previously.

Accordingly, we propose to revise § 414.1270 to reflect these proposals, including our proposals regarding mandatory quality-tiering. We seek comment on these proposals.

c. 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 value-based payment modifier; however, section 1848(p)(4)(C) of the Act requires the value-based payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians based on high performance and decrease for others based on low performance, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value-based payment modifier.

In the CY 2013 PFS final rule with comment period, we adopted a modest payment reduction of 1.0 percent for groups of physicians in Category 1 that elected quality tiering and were classified as low quality/high cost and for groups of physicians in Category 2 (77 FR 69323–24). Although we received comments suggesting that larger payment adjustments (both

upward and downward) would be necessary to more strongly encourage quality improvements, we finalized our proposed adjustments as we believed they better aligned with our goal to gradually phase in the value-based payment modifier. However, we noted that as we gained experience with our value-based payment modifier methodologies, we would likely consider ways to increase the amount of payment at risk (77 FR 69324).

Since last year, we have further considered comments on ways to better encourage improvements in physician efficiency and quality while still gradually phasing in the value-based payment modifier. We agree with commenters on the value of gradually strengthening the incentives to improve performance by offering greater rewards for strong performance along with increased financial risk for poorer performance. As discussed below in section K.5, CMS conducted statistical reliability analysis on the PQRS quality measures and the cost measures contained in the 2010 and 2011 groups and individual physician feedback reports. These reports contained the same PQRS quality measures and cost measures that we will use for the value-based payment modifier. The quality and cost measures in the group reports were statistically reliable at a high level. Moreover, the average reliability score was high for 98 percent of the individually reported PQRS measures and for all of the cost measures (with a case size of at least 20) included in the individual feedback reports. Thus, we believe that we can increase the amount of payment at risk because we can reliably apply a value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals and to smaller groups and to solo practitioners in future years. Therefore, we propose to increase the downward adjustment under the value-based payment modifier from 1.0 percent in CY 2015 to 2.0 percent for CY 2016. That is, for CY 2016, a −2.0 percent value-based payment modifier would apply to groups of physicians subject to the value-based payment modifier that fall in Category 2. In addition, we propose to increase the maximum downward adjustment under the quality-tiering methodology to −2.0 percent for groups of physicians classified as low quality/high cost and to set the adjustment to −1.0 percent for groups classified as either low quality/average cost or average quality/high cost. We propose to revise § 414.1270 and § 414.1275(c) and (d) to reflect the proposed increase to a 2.0 percent adjustment under the value-based payment modifier for the CY 2016 payment adjustment period. We are also making a technical correction to § 414.1275(c) to clarify the PQRS GPRO reporting mechanisms available in CY 2013. Table 62 shows the proposed quality-tiering payment adjustment amounts for CY 2016 (based on CY 2014 performance).

TABLE 62—2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS

CY 2016			
Quality/cost	Low cost	Average cost	High cost
High quality	*+2.0x	*+1.0x	+0.0%
Average quality	*+1.0x	+0.0%	−1.0%
Low quality	+0.0%	−1.0%	−2.0%

*Groups of physicians 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.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period, the upward payment adjustment factor (''x'') would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We note that any funds derived from the application of the downward adjustments to groups of physicians with 100 or more eligible professionals and the downward 2.0 percent adjustment applied to those groups of physicians subject to the value-based payment modifier that fall in Category 2, would be available to all groups of physicians eligible for value-based payment modifier upward payment adjustments. The quality-tiering methodology would continue to provide an additional upward payment adjustment of +1.0x to groups of physicians that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). We seek comments on our proposal to increase the downward value-based payment modifier to 2.0 percent 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 classified as low quality/high cost groups for the CY 2016 payment adjustment period.

d. Performance Period

In the CY 2013 PFS final rule with comment period (77 FR 69314), we adopted a policy that performance on quality and cost measures in CY 2014 will be used to calculate the value-based payment modifier that is applied to items and services for which payment is made under the PFS during CY 2016. We received comments requesting us to close the gap between the end of the performance period (for example, December 31, 2014) and the beginning of the payment adjustment period (for example, January 1, 2016), in order to strengthen the connection between the performance of physicians and groups of physicians and the financial incentives for quality improvement.[3] We understand that many private sector plans start to provide payment adjustment within seven months of close of the performance period.[4]

Because the payment adjustment periods for the value-based payment modifier are tied to the PFS, which is updated on an annual calendar year basis, options to close the one year gap between the close of the performance period and the start of the payment adjustment period center around altering the start and end dates of the performance period, and not the payment adjustment period. As discussed previously in this proposed rule, one option could be to adjust the performance period for quality data reported through the PQRS. In addition, we could calculate the total per capita

[3] See, e.g., Comment of the American College of Surgeons comment on the CY 2013 PFS proposed rule (Aug. 31, 2012).

[4] US GAO, Medicare Physician Payment: Private-Sector Initiatives Can Help Inform CMS Quality and Efficiency Incentive Efforts, GAO–13–160 (Dec. 2012), available at *http://www.gao.gov/assets/660/651102.pdf.*

cost measures on an April 1 through March 31 basis, thus closing the gap by three months.

However, a byproduct of altering the performance periods is that the deadline for submitting quality information would have to occur at the end of the performance period. In addition, the review period during which groups of physicians will be able to review the calculation of the value-based payment modifier would be shortened to allow the necessary system changes to implement the adjustment by the January 1 deadline for implementation of the annual PFS. We seek comment on the potential merits of altering our current performance periods.

Though we appreciate the comments requesting that we shorten the gap between the performance period and the payment adjustment period, we propose to use CY 2015 as the performance period for the value-based payment modifier adjustments that will apply during CY 2017. We believe it is important to propose the performance period for the payment adjustments that will apply in CY 2017, because section 1848(p)(4)(B)(iii) of the Act requires all physicians and groups of physicians to be subject to the value-based payment modifier beginning not later than January 1, 2017. Accordingly, we propose to add a new paragraph (c) to § 414.1215 to indicate that the performance period is CY 2015 for value-based payment modifier adjustments made in the CY 2017 payment adjustment period. We seek comment on this proposal.

We also are striving to provide more timely feedback to stakeholders regarding their cost and quality of care they furnish to Medicare beneficiaries. We note that in CY 2013, we plan to provide physician feedback reports (Quality and Resource Use Reports (QRURs)) starting in mid-September, which is eight and one-half months from the close of the CY 2012 reporting period (that is, December 31, 2012) and five months from the close of the quality data submission period (April 15, 2013) for the GPRO web interface. These QRURs will be made available to all groups of 25 or more eligible professionals and will preview how the groups of physicians would fare under the value-based payment modifier policies, albeit on CY 2012 data, that we established in the CY 2013 final rule with comment period. Moreover, we anticipate that these reports will contain actionable information regarding beneficiaries attributed to the group, thereby enabling physicians in the group to better coordinate care and improve the quality of care furnished. We also are in the process of enhancing our quality reporting and report dissemination infrastructure such that we expect to provide QRURs in 2014 even closer to the end of the performance period.

Despite these efforts, we expect there will always be a gap between the close of the performance period and the beginning of the payment adjustment period to account for various operational processes, albeit one that we are striving to reduce. During this gap, we allow for a three-month claim run out so that physicians are evaluated on complete and accurate information. We standardize the amounts on these claims in order to calculate the cost measures. This process takes one month. Concurrent with these two processes, we obtain the data reported for quality measurement and calculate the PQRS measures—a process which takes at least six months. In addition, we then calculate each group's cost and quality composites and implement the quality-tiering methodology. We then produce and verify the reports. These processes combined take approximately eight to nine months. We are striving to find ways to make these processes more efficient as we gain more experience producing these reports.

e. Quality Measures

In the CY 2013 PFS final rule with comment period (77 FR 69315), we aligned our policies for the value-based payment modifier for CY 2015 with the PQRS reporting mechanisms available to groups of physicians in CY 2013, such that data that a group of physicians submitted for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2013 would be used for calculating the quality composite under the quality-tiering approach for the value-based payment modifier for CY 2015. Moreover, all of the quality measures for which groups of physicians are eligible to report under the PQRS are used to calculate the group of physicians' value-based payment modifier for CY 2015, to the extent the group of physicians submits data on such measures. We also established a policy to include three additional quality measures (outcome measures) for all groups of physicians subject to the value-based payment modifier: (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).

We believe it is important to continue to align the value-based payment modifier for CY 2016 with the requirements of the PQRS, because quality reporting is a necessary, but not sufficient, component of quality improvement. We also seek not to place an undue burden on physicians to report such data so that they can furnish care to beneficiaries in an efficient manner. We propose to include, therefore, for purposes of the value-based payment modifier for CY 2016, all of the PQRS GPRO reporting mechanisms available to group practices for the PQRS reporting periods in CY 2014 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2014. Accordingly, we also propose to update our regulations at § 414.1220 to reflect this proposal. We note that the criteria for satisfactory reporting of data on PQRS quality measures for individual eligible professionals via qualified registries for the CY 2014 PQRS incentive and CY 2016 PQRS payment adjustment permits the use of a 6-month reporting period (Tables 24 and 25). We believe that data submitted via qualified registries for this 6-month reporting period would be sufficiently reliable on which to base a group of physicians' quality composite score under the value-based payment modifier because in order for us to use the data to calculate the score, we would require data for each quality measure on at least 20 beneficiaries, which is the reliability standard for the value-based payment modifier (77 FR 69322–69323). Given this level of reliability, we believe a six-month reporting period would be comparable to a 12-month reporting period for the purpose of evaluating the quality of care furnished by a group of physicians subject to the value-based payment modifier. We seek comment on this proposal.

We also propose to utilize all of the quality measures that are available to be reported under these various PQRS reporting mechanisms, including quality measures reported through qualified clinical data registries, to calculate a group of physicians' value-based payment modifier in CY 2016 to the extent that a group of physicians submits data on these measures. In addition, we propose that groups of physicians with 25 or more eligible professionals will be able to elect to have included in their value-based payment modifier for CY 2016 the patient experience of care measures collected through the PQRS CAHPS

survey for CY 2014. These reporting mechanisms and the patient experience measures are described in Tables 24 through 27. We note that the three outcome measures that we finalized in the CY 2013 PFS final rule with comment period and in § 414.1230—the two composites of rates of potentially preventable hospital admissions and the all-cause hospital readmission measure—would continue to be included in the quality measures used for the value-based payment modifier in CY 2016.

Although we have received comments to require a core set of quality measures for the value-based payment modifier, we believe it is premature to require reporting on limited set of measures by all physicians until physicians have had a chance to choose measures that are meaningful to their practice. As we indicated previously, our primary focus is on measurement and alignment during the phase-in of the value-based payment modifier, because we believe it is difficult to maintain high-quality care and improve quality and performance without measurement. Thus, it is important to provide physicians and groups of physicians flexibility on the data they report for quality measures.

For those groups of physicians subject to the value-based payment modifier in CY 2016 whose eligible professionals participate in the PQRS as individuals rather than as a group practice under the GRPO (that is, groups of physicians that are assessed under the 70 percent threshold), we propose to calculate the group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. If all of the eligible professionals in a group of physicians subject to the CY 2016 value-based payment modifier satisfactorily participate in a PQRS qualified clinical data registry in CY 2014 and we are unable to receive quality performance data for those eligible professionals for the reasons discussed above, for purposes of the value-based payment modifier, we propose to classify the group's quality composite score as ''average'' under the quality-tiering methodology, because we would not have data to reliably indicate whether the group should be classified as high or low quality under the quality-tiering methodology. Accordingly, we also propose to add a new subsection to our regulations at § 414.1270 to reflect our proposals about how to assess quality performance for groups assessed under the 70 percent threshold. We seek comment on these proposals.

We note that when the value-based payment modifier applies to all physicians and groups of physicians in CY 2017 based on performance during CY 2015, we anticipate continuing our policy to align with the PQRS group reporting for all groups of physicians of two or more eligible professionals, and we anticipate permitting physicians who are solo practitioners to use any of the PQRS reporting mechanisms available to them under the PQRS for reporting periods in CY 2015 for purposes of the value-based payment modifier in CY 2017. Although we are not proposing to adopt this policy in this proposed rule, we seek comment on this approach to align the quality measures and reporting mechanisms used in the PQRS for purposes of the value-based payment modifier.

f. Inclusion of the Medicare Spending per Beneficiary Measure in the Value-Based Payment Modifier Cost Composite

In the CY 2013 PFS final rule with comment period (77 FR 69316), we established a policy to include five cost measures in the value-based payment modifier cost composite. The five measures are total per capita costs (both Parts A and B) and total per capita costs for beneficiaries with four specific chronic conditions: Chronic obstructive pulmonary disease (COPD), heart failure, coronary artery disease (CAD), and diabetes. We stated that the value-based payment modifier should incorporate additional measures that are consistent with the National Quality Strategy and other CMS quality initiatives. As a step toward that goal, beginning with the CY 2016 value-based payment modifier, we propose to expand the cost composite to include an additional measure, the Medicare Spending per Beneficiary (MSPB) measure (with one modification as discussed below). This section discusses the background of the MSPB measure and our proposals to incorporate it into the value-based payment modifier beginning with the CY 2016 payment adjustment period and beyond.

Background on the implementation of the MSPB measure for other CMS quality programs. We finalized the MSPB measure for use in the Hospital IQR Program in the FY 2012 IPPS final rule to further Medicare's transformation from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation and to help address the critical issue of health care costs (76 FR 51618–27). We finalized the MSPB measure for inclusion in the Hospital VBP Program in the FY 2013 IPPS final rule as an important first step toward identifying value in healthcare. In that rule, we expressed our belief that this measure provides an incentive for hospitals to build stronger relationships with and better understand the providers and suppliers that furnish care for their patients before and after an acute care hospitalization (77 FR 53585). When viewed in light of other quality measures, as a part of the value-based payment modifier measure set, we believe that the measure would enable us to align incentives and similarly recognize physician groups involved in the provision of high-quality care at a lower cost to Medicare. This measure also addresses physician care associated with acute inpatient hospitalizations and post-acute care. In its recently-released ''Interim Report of the Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care: Preliminary Committee Observations,'' the Institute of Medicine (IOM) observed that, ''Geographic variation in total Medicare spending is strongly influenced by the utilization of post-acute care.'' [1] Medicare spending post-hospital discharge is a significant source of variation in the MSPB measure rates, with spending unrelated to readmissions being the largest source of variation in those post-discharge Medicare payments. As part of the value-based-payment modifier measure set, the MSPB measure would recognize and enable CMS to assess groups of physicians' performance relating to post-acute care spending, which is a ''major source of unexplained variation in Medicare spending.'' [1]

We propose that this measure would be added to the total per capita costs for all attributed beneficiaries domain of the value-based payment modifier. Thus, there would be two measures in the total per capita costs for all attributed beneficiaries domain—the total per capita costs measure and the MSPB measure—each weighted equally in the domain. We considered placing this measure in the total per capita costs for all attributed beneficiaries with specific conditions domain; however, we are not proposing to do so because the MSPB measure is similar to the total per capita costs measure (because it includes all costs incurred by a beneficiary), albeit one that is related to the totality of services furnished surrounding an inpatient hospitalization, and thus belongs in the total per capita costs for all attributed beneficiaries domain. Moreover, we intend to propose in future rulemaking

to replace the four measures in the total per capita costs for all attributed beneficiaries with specific conditions domain with cost measures derived from the CMS Episode Grouper and other episode-based costs derived from our recent and ongoing work with many specialty societies.[5] We solicit comments on these potential changes to the condition-specific cost measures as well as on the other elements of the cost composite in preparation for the CY 2015 performance period affecting payment adjustment year CY 2017.

We currently use the MSPB measure in two other CMS quality initiatives, the Hospital Inpatient Quality Reporting (IQR) and Hospital Value-Based Purchasing (VBP) Programs. We believe that its inclusion in the value-based payment modifier will help to align performance incentives across the delivery system. By focusing on the cost of care and encouraging avoidance of unnecessary services, the measure also addresses one of the National Quality Strategy aims of better care: Care that is affordable. This measure has been submitted to the National Quality Forum for endorsement, and it was supported by the Measures Application Partnership for inclusion in both the Hospital IQR and VBP Programs.

Construction of the MSPB measure. The MSPB measure used for the Hospital IQR and VBP Programs is constructed of services furnished surrounding hospitalizations (''index admissions''). The measure includes all Medicare Part A and Part B payments during an MSPB episode. An MSPB episode spans from 3 days prior to an index admission at a subsection (d) hospital[6] through 30 days post discharge with certain exclusions. Certain hospitalizations at subsection (d) hospitals do not represent index admissions for the MSPB measure. Admissions that result in a transfer from one acute hospital to another, episodes that occur fewer than 30 days before the end of the performance period, or episodes during which the beneficiary is not enrolled in both Part A and Part B Medicare do not count as index admissions. Costs for each episode are risk adjusted for age and severity of illness, and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. The payment standardization is the same methodology used for the existing total per capita cost measures included in the value-based payment modifier.

To calculate a hospital's MSPB amount, the payment-standardized costs for all index admissions are summed and divided by the sum of the expected costs from the risk adjustment model. This ratio is then multiplied by the national average MSPB episode cost to give the hospital's MSPB amount. Because the Hospital IQR and VBP Programs apply to subsection (d) hospitals, we attribute a MSPB index admission to the hospital at which an index admission occurs, and we calculate the MSPB amount at the hospital level.

After determining an individual hospital's MSPB amount, we divide it by the national median MSPB amount to calculate a ratio. This ratio is then converted to a percentage which is the MSPB measure rate that we report publicly on Hospital Compare under the Hospital IQR Program and use to generate a measure score for the Efficiency domain under the Hospital VBP Program. In the context of the value-based payment modifier, we propose a slightly revised calculation. We propose not to convert the MSPB amount to a ratio as is done to compute a hospital's MSPB measure, but rather use the MSPB amount as the measure's performance rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for a detailed description of the MSPB measure that is used in the Inpatient Quality Reporting program and the HVBP program. Additional information on the measure, including a detailed specification document (entitled ''MSPB Measure Information Form'') and the payment standardization methodology (entitled ''CMS Price Standardization'') can be found in the ''Measure Methodology'' section at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*. We seek comment on our proposals to include the MSPB measure (as modified per the discussion above) in the value-based payment modifier cost composite and to add the measure to the total per capita costs for all attributed beneficiaries domain. We also propose to revise the regulations at § 414.1235 to include the Medicare Spending per Beneficiary measure in the set of cost measures for the value-based payment modifier and § 414.1260(b)(1)(i) to include the Medicare Spending per Beneficiary measure in the total per capita costs for all attributed beneficiaries domain. As stated previously, all of our proposals related to the MSPB measure would apply beginning with the CY 2016 value-based payment modifier.

Attribution of the MSPB measure to physician groups. Unlike the Hospital IQR and VBP Programs, in which we attribute the MSPB index admission to the hospital at which the index admission occurred, we need to develop a method to attribute the MSPB episode to groups of physicians to include the measure in the value-based-payment modifier. We propose to attribute an MSPB episode to a group of physicians subject to the value-based payment modifier (as identified by a single TIN), when any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Thus, the same index admission and MSPB episode could be attributed to more than one group of physicians.

We believe that attribution of the MSPB episode to all groups of physicians from which an eligible professional submits a Part B claim for a service rendered during the hospitalization is the best way to assign responsibility for, and encourage greater coordination of, care furnished to Medicare beneficiaries who are hospitalized. Based on CY 2011 claims data, the proposed approach would enable approximately 11,419 groups of physicians with at least 10 eligible professionals to have an MSPB measure score included in their cost composite.[7] Our proposed approach incentivizes hospitals and physicians to furnish efficient, effective care during a hospitalization and to coordinate post-discharge care to avoid unnecessary services and preventable readmissions. Further, we believe that this attribution approach fosters shared accountability between hospitals and physicians for the care they furnish to Medicare beneficiaries who are hospitalized. We propose to add a new paragraph (b) to § 414.1240 to indicate that a MSPB episode would be attributed to a group

[5] Our recent activities relating to developing Medicare-specific episodes using the CMS Episode grouper and development of other episode costs are discussed in the Physician Feedback Program section below.

[6] Section 1886(d)(1)(B) of the Social Security Act defines such hospitals as those in the 50 States and the District of Columbia other than psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly under 18 years old, hospitals whose average inpatient length of stay exceeds 25 days, and hospitals involved extensively in treatment for, or research on, cancer.

[7] We note that, based on 2011 claims, many of these 11,419 groups would only have the MSPB measure included in the cost composite because the physicians in the groups do not provide primary care services and thus do not have attributed beneficiaries for the five annual total per capita cost measures.

of physicians subject to the value-based payment modifier if any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Groups of physicians would have a Medicare Spending per Beneficiary measure score included in their cost composite based on the proposed attribution methodology for the MSPB. We welcome public comment on our proposal.

We also considered attributing the MSPB episode to physician groups from which an eligible professional in the group billed a part B claim for a service rendered at any time during the Medicare Spending per Beneficiary episode (that is, from 3 days prior to an index admission through 30 days post-discharge). This attribution approach would place an even stronger emphasis on shared accountability for care provided to Medicare beneficiaries who are hospitalized, both during and after their hospitalization. Based on 2011 claims data, we estimate that attribution to any physician group from which a eligible professional billed a part B claim at any time during the episode would enable an additional 3,017 groups of physicians with 10 or more eligible professionals to receive an MSPB measure performance rate for inclusion in the cost composite, as compared to our proposed attribution approach which considers only those eligible professionals who bill a Part B claim during the hospitalization. We welcome public comment on the alternative attribution approach under which we would attribute an MSPB episode to a physician group if any eligible professional in the group billed a Part B service during the 3 days prior to an index admission through 30 days post hospital discharge.

In addition to the proposed attribution method above, we considered several other methods to attribute the MSPB measure to physician groups. For example, the MSPB episode could be attributed solely to the group of physicians that provided the plurality of Part B services billed either: (1) During the entire MSPB episode (that is three days prior to hospital admission through 30 days post discharge); or (2) during the index hospitalization only. By ''plurality'' of services, we mean the highest total dollar amount paid by Medicare to any group of physicians who provided Part B services during a given portion of an episode (either the full episode or the hospitalization only). The group of physicians need not have provided the majority of the services paid by Medicare during a given portion of an episode, but rather to have provided services for which Medicare paid more than it did to any other group of physicians during that portion of an episode. This method is a single attribution approach unlike our proposal which is a multi-attribution approach.

Using 2011 claims, we analyzed the number of TINs, comprised of 10 or more eligible professionals, that would be attributed an MSPB measure rate under these alternative attribution methods given a minimum of 20 MSPB episodes required. Our analyses revealed that 7,799 TINs (out of approximately 17,000 TINs (see Table 61)) would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the group of physicians that received the plurality of Medicare Part B payments during the entire MSPB episode. This represents a 46% decrease from the 11,419 TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the entire episode, as we proposed above. Our analysis also showed that 7,582 TINs would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the physician group that billed the plurality of Medicare Part B payments during the index admission. This represents a 34% decrease from the 14,436 TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the index admission.

We considered these attribution methods because they represent methods to identify groups of physicians that were ''most responsible'' for the Part B Medicare payments made during the episode. We are not proposing these methods, because we believe our proposed multiple attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during a hospitalization. We believe our proposed attribution approach is further supported by the higher number of TINs that will be able to receive an MSPB measure rate under that methodology. We seek comment, however, on these two single alternative attribution approaches we considered: Attributing an MSPB episode to the group of physicians that provided the plurality of Part B services billed either during the entire MSPB episode or during the index hospitalization only.

In addition, we considered a hybrid attribution method: Attribute MSPB episodes to all TINs from which an eligible professional provided services representing at least 35 percent of the total Medicare Part B payments made either: (1) During the entire MSPB episode (that is three days prior to hospital admission through 30 days post discharge); or (2) during the index hospitalization only. This alternative could result in multiple attribution, if two eligible professionals from different TINs each provided services representing at least 35 percent of the Part B Medicare payments during one of the episode portions described above (either the full episode or during the index admission only). The rationale for this attribution approach is that it ensures that a group of physicians had responsibility for a significant portion of the Medicare beneficiary's care during a given portion of the MSPB episode. We are not proposing this alternative, because we believe that our proposed attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during and after a hospitalization. We welcome public comment on this alternative attribution approach based on provision of services representing at least 35 percent of Medicare Part B payments made either during the entire MSPB episode or during the index hospitalization only.

Reliability standard for the Medicare Spending per Beneficiary measure for the value-based payment modifier. We propose that a group of physicians would have to be attributed a minimum of 20 MSPB episodes during the performance period to have their performance on this measure included in the value-based payment modifier cost composite. Table 63 shows the MSPB measure's reliability at various minimum numbers of episodes for all Medicare-enrolled TINs with at least one EP (not just TINs of 10 or more eligible professionals) from May 2011 through December 2011. In this context, reliability is defined as the extent to which variation in the measure's performance rate is due to various in the cost of services furnished by groups of physicians rather than random variation due to the sample of cases observed. Potential reliability values range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in the difference is performance across groups of physicians. Generally, reliabilities in the 0.40–0.70 range are often considered

moderate and values greater than 0.70 high.

TABLE 63—RELIABILITY OF MEDICARE SPENDING PER BENEFICIARY MEASURE FOR ALL TINS WITH AT LEAST ONE ELIGIBLE PROFESSIONAL

[May 2011–December 2011]

MSPB episodes attributed	Number of TINs	Percent of TINs	Mean risk-adjusted standardized cost per MSPB episode	Average reliability
1–9	59,419	47	$20,493	0.65
10–19	12,332	10	21,260	0.79
20–29	7,774	6	21,225	0.83
30–39	5,839	5	21,340	0.85
40–49	4,511	4	21,324	0.87
50–99	12,648	10	21,353	0.89
100–124	3,702	3	21,403	0.91
125–149	2,761	2	21,342	0.92
150–174	2,134	2	21,316	0.93
175–199	1,673	1	21,119	0.93
200+	14,933	12	20,562	0.96

We also considered a minimum number of 10 episodes. The advantage of this lower minimum number is that it would enable us to calculate the MSPB measure for an additional 12,332 physician groups once we apply the value-based payment modifier to all physicians and groups of physicians. With a minimum of 10 cases, the measure is still very reliable, as illustrated in the Table 63. We are proposing the minimum of 20 cases for initial implementation of this measure in the cost composite beginning with the CY 2016 value-based payment modifier because it strikes a balance between maintaining high reliability and including a large number of physician groups. We note that this reliability standard we are proposing is the same one we adopted in the CY 2013 PFS final rule with comment period that applies to quality and cost measures used in the value-based payment modifier (77 FR 69323). We welcome public comment on our proposed minimum of 20 episodes for inclusion of the Medicare Spending per Beneficiary measure in the cost composite for the value-based payment modifier and on the alternative 10 episode minimum that we considered.

g. Refinements to the Cost Measure Composite Methodology

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 of physicians subject to the value-based payment modifier that includes five payment-standardized and risk-adjusted cost measures. To calculate the each group's cost measures, we first attribute beneficiaries to the group of physicians. We attribute beneficiaries using a two-step attribution methodology that is used for the Medicare Shared Savings Program and the PQRS GPRO and that focuses on the delivery of primary care services (77 FR 69320). We have observed that groups of physicians that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries and, thus, we are unable to calculate reliable cost measures for those groups of physicians (77 FR 69323). Given this development, we propose that, to the extent that we are unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the value-based payment modifier and thus are unable to calculate any of the cost measures with at least 20 cases, the group of physicians' cost composite score would be classified as ''average'' under the quality-tiering methodology. We believe this policy is reasonable because we would have insufficient information on which to classify the group of physicians' costs as ''high'' or ''low'' under the quality-tiering methodology. Moreover, we believe that to the extent a group of physicians' quality composite is classified as ''high'' or ''low,'' the groups of physicians' value-based payment modifier should reflect that classification. Accordingly, we propose to add a new paragraph at § 414.1270 to reflect this proposal that groups of physicians in Category 1 for which we attribute fewer than 20 cases to calculate any cost measure would have their cost composite classified as ''average'' cost. We seek comment on this proposal.

Once we calculate the cost measures for each group of physicians subject to the value-based payment modifier, we create the cost composite by calculating a standardized score for each cost measure and then placing the measures into one of two equally weighted domains: (1) The total per capita costs for all attributed beneficiaries domain; and (2) the total per capita costs for attributed beneficiaries with specific conditions domain. This standardized score is referred to in statistical terms as a Z-score. To arrive at the standardized score for each cost measure, we compare the performance for each group's cost measures to the benchmark (national mean) of other groups subject to the value-based payment modifier (peer group) for the same performance year. Specifically, we calculate the benchmark for each cost measure as the national mean of the performance rates among all groups of physicians to which beneficiaries are attributed and that are subject to the value-based payment modifier. For example, for CY 2015, the cost measures of groups of 100 or more eligible professionals (EPs) will be compared to the cost measures of other groups of 100 or more EPs. We also noted that we would consider the effects of this policy over the next several years as we implement this program and may consider changes to these policies through future rulemaking.

Using 2011 claims data, we have since examined the distribution of the overall total per capita cost measure among all groups of physicians with one or more eligible professionals to determine whether comparisons at the group level would be appropriate once we apply the value-based payment modifier to smaller groups of physicians and solo practitioners. We found that our current peer grouping methodology could have varied impacts on groups of physicians

that are comprised of different physician specialties. This result occurs because the peer group for the per capita cost benchmarks is based on a national mean calculated among all groups of physicians subject to the value modifier rather than determined more narrowly (for example, within a physician specialty).

For certain physician specialties, the types of services furnished typically have higher than average or lower than average costs, and thus can affect the group's cost measures. For example, medical and other types of oncologists tend to treat relatively costly beneficiaries and bill for expensive Part B drugs, which can increase mean total per capita costs for oncologists as a whole. By contrast, dermatologists and ophthalmologists, for example, perform relatively low cost procedures in an outpatient setting and, thus, their total per capita cost measures are low. Moreover, to the extent that physicians in groups of physicians work together to provide services to the same beneficiaries, groups of physicians with a large proportion of high or low-cost specialists can affect the level of the group's cost measures. Although the cost data are adjusted to account for the relative risk of patients, the effects of these adjustments do not fully offset this result at the physician and physician group level.

To address this issue beginning with the CY 2016 value-based payment modifier, we considered two methods that account for the group practice's specialty composition so that our quality-tiering methodology produces fair peer group comparisons and, ultimately, correctly ranks group of physicians based on actual performance. Taking account of physician specialties in making cost comparisons is similar to the approach we have used in the CY 2010 and CY 2011 Quality and Resource Use Reports (QRURs) for individual physicians in which we made cost comparisons at the individual physician specialty level.

The first method, ''specialty adjustment,'' accounts for the specialty composition of the group prior to computing the standardized score for each cost measure. This method enables us to develop comparable benchmarks for the risk-adjusted cost measures against which to evaluate groups of physicians of smaller size who often have fewer or single specialty composition. More specifically, we would adjust the standardized score methodology to account for a group's specialty composition using three steps:

Step 1: Create a specialty-specific expected cost based on the national average for each cost measure (referred to as the ''national specialty-specific expected costs''). To do so, we would attribute beneficiaries to a group using the plurality of primary care services methodology that we finalized in the CY 2013 PFS final rule with comment period (77 FR 69316). For each specialty, we would calculate the average cost of beneficiaries attributed to groups of physicians with that specialty, weighted by the number of EPs in each group.

Step 2: Calculate the ''specialty-adjusted expected cost'' for each group of physicians by weighting the national specialty-specific expected costs by the group's specialty composition of Part B payments. That is, the specialty-adjusted expected cost for each group is the weighted average of the national specialty-specific expected cost of all the specialties in the group, where the weights are each specialty's proportion of the group's Part B payments. The Part B payments for each specialty are determined based on the payments to each EP in the group, and each EP is identified with one specialty based on its claims.

Step 3: Divide the total per capita cost by the specialty-adjusted expected cost, and multiply this ratio by the national average per capita cost so that we can convert this ratio to a dollar amount (referred to as the ''specialty-adjusted total per capita cost'') that can then be used in the standardized (Z-) score to determine whether a group can be classified as high cost, low cost, or average.

Below, we illustrate the three steps of the specialty adjustment to the standardized score with an example. Assume for simplicity that only two TINs and two specialties exist: TIN 1 and TIN 2, and Specialty A and Specialty B. For this example, assume that the total per capita costs and specialty shares are as shown in Table 64.

TABLE 64—EXAMPLE OF CALCULATING SPECIALTY-ADJUSTED TOTAL PER CAPITA COST: ASSUMPTIONS

TIN	Risk-Adjusted per capita cost	Number of attributed beneficiaries	Number of EPs in TIN by specialty type A or B	Specialty share of EPs in TIN	Specialty share of part B payments in TIN
TIN 1	$12,000	1,500	A: 10; B: 30	A: 25%; B: 75%	A: 35%; B: 65%
TIN 2	8,000	2,000	A: 21; B: 39	A: 35%; B: 65%	A: 60%; B: 40%

Step 1: To compute the national specialty-specific expected cost for a specialty across all TINs, we first calculate the numerator, which is the product of each TIN's total per capita cost times its weight (the number of attributed beneficiaries times that specialty's share of the TIN's EPs times the number of EPs of that specialty in that TIN), summed across all TINs. This sum is divided by the denominator, which is the sum across all TINs of the same weights that were used in the numerator. For this example, the national specialty-specific expected cost for Specialty A is ($12,000 * 1,500 * 25% * 10 + $8,000 * 2,000 * 35% * 21)/(1,500 * 25% * 10 + 2,000 * 35% * 21) = $8,813. Similarly, the national specialty-specific expected cost for Specialty B is ($12,000 * 1,500 * 75%*30 + $8,000 * 2,000 * 65% * 39)/(1,500 * 75% * 30 + 2,000 * 65% * 39) = $9,599.

National Specialty-Specific Expected Cost, by Specialty (step 1)

Specialty A: $8,813

Specialty B: $9,599

Step 2: To calculate the specialty-adjusted expected cost for each group (TIN), we would multiply the above national specialty-specific expected costs by each group's proportion of specialty-specific Part B payments. For each TIN, we compute the product of the TIN's proportion of specialty-specific Part B payments, summed across all specialty types of the TIN. In our example, the specialty-adjusted expected cost for TIN 1 would be computed as 35% * $8,813 + 65% * $9,599 = $9,324. Similarly, the specialty-adjusted expected cost for TIN 2 would be 60% * $8,813 + 40% * $9,599 = $9,127.

Specialty-Adjusted Expected Cost, by TIN (step 2)

TIN 1: $9,324

TIN 2: $9,127

Step 3: We divide the total per capita cost by the specialty-adjusted expected cost and multiply this ratio by the national average per capita cost, to convert this ratio to a dollar amount.

Assuming the national average per capita cost is $9,714, we can compute the specialty-adjusted total per capita cost for each TIN, as shown in Table 65.

TABLE 65—EXAMPLE OF CALCULATING SPECIALTY-ADJUSTED TOTAL PER CAPITA COST: CALCULATIONS

COLUMN	A	B	C	D
TIN	Total per capita cost	Specialty-adjusted expected cost	National average per capita cost	Specialty-adjusted total per capita cost: ((column A/ column B) * column C)
TIN 1	$12,000	$9,324	$9,714	$12,502
TIN 2	8,000	9,127	9,714	8,514

The figure in the rightmost column (column D) is the specialty-adjusted total per capita cost that is used to compute a group's standardized (Z-) score. As can be seen, the specialty-adjusted total per capita cost for use in the standardized score is $12,502 for TIN 1 and $8,514 for TIN 2.

To illustrate the impact of the specialty adjustment methodology, we examined the distribution, by specialty, of the overall specialty-adjusted total annual per capita cost measure based on 2011 claims for group of physicians with 1 or more eligible professionals. Table 66 includes the percentage of physicians in each specialty that practice in groups of 1 or more eligible professionals with 20 or more attributed beneficiaries and that, based only on this one measure, would be classified into low, average, and high cost groups. Table 66 does not represent all of the physicians within that specialty, rather only those that practice in groups of physicians with at least 20 attributed beneficiaries.

TABLE 66—PERCENTAGE OF PHYSICIANS PRACTICING IN GROUPS WITH 1 OR MORE ELIGIBLE PROFESSIONALS, WITH AT LEAST 20 BENEFICIARIES, CLASSIFIED BY COST

Specialty	Percentage of eligible professionals in groups (TINs) classified as		
	Low cost (percent)	Average cost (percent)	High cost (percent)
Addiction medicine	4.7	94.1	1.2
Allergy/immunology	5.3	92.4	2.3
Anesthesiology	1.6	93.5	4.9
Cardiac Electrophysiology	1.9	95.7	2.4
Cardiac surgery	0.5	92.9	6.6
Cardiology	4.4	92.2	3.3
Chiropractic	3.1	88.7	8.2
Colorectal surgery	3.1	89.2	7.6
Critical care (intensivists)	1.7	91.9	6.4
Dermatology	30.6	68.0	1.4
Diagnostic radiology	0.7	92.7	6.6
Emergency medicine	3.7	89.1	7.2
Endocrinology	9.2	89.1	1.7
Family practice	1.3	91.7	7.0
Gastroenterology	4.4	93.3	2.2
General practice	5.7	84.8	9.5
General surgery	1.6	90.1	8.3
Geriatric medicine	1.5	83.8	14.7
Geriatric Psychiatry	0.0	82.5	17.5
Gynecologist/oncologist	1.7	88.5	9.8
Hand surgery	3.1	95.6	1.3
Hematology	0.7	89.1	10.2
Hematology/oncology	1.0	87.3	11.8
Hospice and Palliative Care	0.3	87.9	11.8
Infectious disease	2.5	90.6	6.9
Internal medicine	1.3	87.4	11.3
Interventional Pain Management	2.9	89.7	7.4
Interventional radiology	0.7	93.0	6.2
Maxillofacial surgery	0.9	94.7	4.4
Medical oncology	0.5	83.4	16.1
Nephrology	7.6	89.3	3.0
Neurology	5.0	92.4	2.6
Neuropsychiatry	4.0	90.7	5.3
Neurosurgery	1.4	83.7	14.9
Nuclear medicine	2.2	90.5	7.3
Obstetrics/gynecology	7.7	89.0	3.3

TABLE 66—PERCENTAGE OF PHYSICIANS PRACTICING IN GROUPS WITH 1 OR MORE ELIGIBLE PROFESSIONALS, WITH AT LEAST 20 BENEFICIARIES, CLASSIFIED BY COST—Continued

Specialty	Percentage of eligible professionals in groups (TINs) classified as		
	Low cost (percent)	Average cost (percent)	High cost (percent)
Ophthalmology	17.7	80.9	1.5
Oral surgery (dentists only)	1.5	92.4	6.1
Orthopedic surgery	3.1	91.5	5.5
Osteopathic manipulative medicine	5.7	85.8	8.5
Otolaryngology	13.4	84.3	2.3
Pain Management	1.5	86.0	12.6
Pathology	2.4	91.2	6.4
Pediatric medicine	1.2	92.6	6.2
Peripheral vascular disease	0.0	94.4	5.6
Physical medicine and rehabilitation	2.1	87.9	9.9
Plastic and Reconstructive surgery	4.2	90.4	5.4
Podiatry	2.2	91.3	6.5
Preventive medicine	3.0	91.3	5.6
Psychiatry	5.0	88.8	6.2
Pulmonary disease	3.3	92.0	4.7
Radiation oncology	4.4	83.5	12.1
Rheumatology	3.9	93.5	2.6
Single or Multispecialty clinic or group practice	5.9	85.1	9.1
Sports Medicine	2.6	94.8	2.6
Surgical oncology	1.6	82.5	16.0
Thoracic surgery	0.1	92.3	7.6
Urology	3.9	93.2	2.9
Vascular surgery	0.3	93.7	6.0

Under this methodology, we would perform this specialty adjustment prior to computing the standardized score for all six cost measures included in the value-based payment modifier: The total per capita cost measure, the four total per capita cost measures for beneficiaries with specific conditions, and the MSPB measure. The specialty adjustment for the four condition-specific total per capita cost measures is identical to the total per capita cost measure that was described above. The specialty adjustment for the MSPB cost measure is analogous to that described above for the total per capita cost measure, except that ''number of beneficiaries'' is replaced with ''number of episodes'' and ''per capita cost'' is replaced with ''per episode cost.'' Thus, each cost measure will have its own set of specialty-specific expected costs.

The second method, ''comparability peer grouping,'' constructs peer groups for each physician group practice by identifying group practices with the nearest comparable specialty mix.[8] After doing so, we would then calculate a benchmark for the peer group and then use the benchmark to calculate the group's standardized score for that measure. Under this approach, two group practices would be considered to have the same specialty mix if the share of physicians of each specialty is within a defined range for both group practices. For the purposes of computing peer groups, group practices also could be stratified by size, as measured by number of eligible professionals billing under the group practice's TIN. A group practice's peer group, however, would include a minimum number of peers (that is, group practices with similar specialty mixes) to ensure a reliable comparison. If there were fewer than the designated number of other group practices with the group practice's same specialty mix in the group practice's size category, group practices would be added to the peer group based on the next level of comparability in order to obtain the minimum number of group practices. Group practices that had a specialty mix more comparable to the practice's own mix would receive greater weight in the peer group. Among the identified peers sharing the same specialty mix, those with the most cases would receive the greatest weight.

We tested this method, based on 2011 claims, using a sample of 870 group practices of 25 or more EPs. The results showed that the comparability peer grouping approach reduced the average difference between the group's performance and benchmark rate compared to the difference between the group's performance and benchmark as computed based on the methodology we established in the CY 2013 PFS final rule with comment period and which does not consider the specialty composition of the group of physicians. Moreover, further analysis showed that this methodology consistently ranked groups of physicians. In other words, groups of physicians in the top and bottom 5th percentiles were consistent using this approach.

On balance, we believe that the first method, the specialty benchmarking method, is preferable to account for the specialty composition of the group of physicians when making peer group comparisons and creating the standardized score for the cost measures for the value-based payment modifier. We also believe this methodology allows us to apply the value-based payment modifier to smaller size groups and solo practitioners. This methodology creates one national benchmark for each cost measure. Moreover, all groups of physicians (regardless of size) are assessed against that benchmark in creating the group of physicians' standardized score. As discussed in the CY 2013 PFS final rule with comment period, we believe national benchmarks are appropriate for the value-based payment modifier (77

[8] For a description of this type of method, see, for example, Margaret M. Byrne, et al., Method to Develop Health Care Peer Groups for Quality and Financial Comparisons Across Hospitals. April 2009. HSR: Health Services Research 44:2, Part I: 577–592.

FR 69322). Although the calculations discussed above may be very detailed, they are transparent and we can provide each group of physicians with information on how its costs were benchmarked in its Quality and Resource Use Report.

By contrast, the second method, comparability peer grouping, requires us to develop a transparent way to define which groups of physicians are similar enough to be included in each group of physicians' peer group. This approach also creates a different benchmark for each group of physicians, which may make it more difficult for groups of physicians to understand how their costs are benchmarked. Notwithstanding these downsides, the comparability peer grouping method treats each group of physicians as a whole, rather than as a sum of its parts as in the specialty benchmarking method, and thus may have more acceptability among physicians. Moreover, treating the group of physicians as a whole also reinforces the shared accountability aspect of the value-based payment modifier.

Given these considerations, we propose to use the first method, the specialty benchmarking method, to create the standardized score for each group's cost measures beginning with the CY 2016 value-based payment modifier. Accordingly, we propose to amend our regulations at § 414.1255 to include this policy in our cost composite methodology. We seek comment on our proposals, including comments on ways to streamline or enhance the calculation mechanics and to make the specialty adjustments more transparent and easily understood. We also seek comment on the alternative method, the comparability peer grouping method. We propose 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. We understand that many physicians believe our current specialty designations may mask sub-specialist care furnished. We note that the procedures for obtaining a CMS specialty code are available at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html.*

Regardless of the method chosen, we will continue to monitor the effects of this policy over the next several years as we implement this program and may consider changes to these policies through future rulemaking.

5. Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to 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 CY 2012, we disseminated both group and individual QRURs, based on CY 2011 performance, to a wider audience than the CY 2010 reports. These reports contained improvements and enhancements suggested by the recipients of the CY 2010 reports to provide meaningful and actionable information for quality improvement. In addition, in May 2013, we provided supplemental QRURs to the group report recipients that featured episode-based costs for care of pneumonia and several acute and chronic cardiac conditions. We derived these episode-based costs using the newly developed CMS Episode Grouper software required by section 1848(n)(9)(ii) of the Act.

a. CY 2011 Physician Group Feedback Reports Based on CY 2011 Data and Disseminated in CY 2012

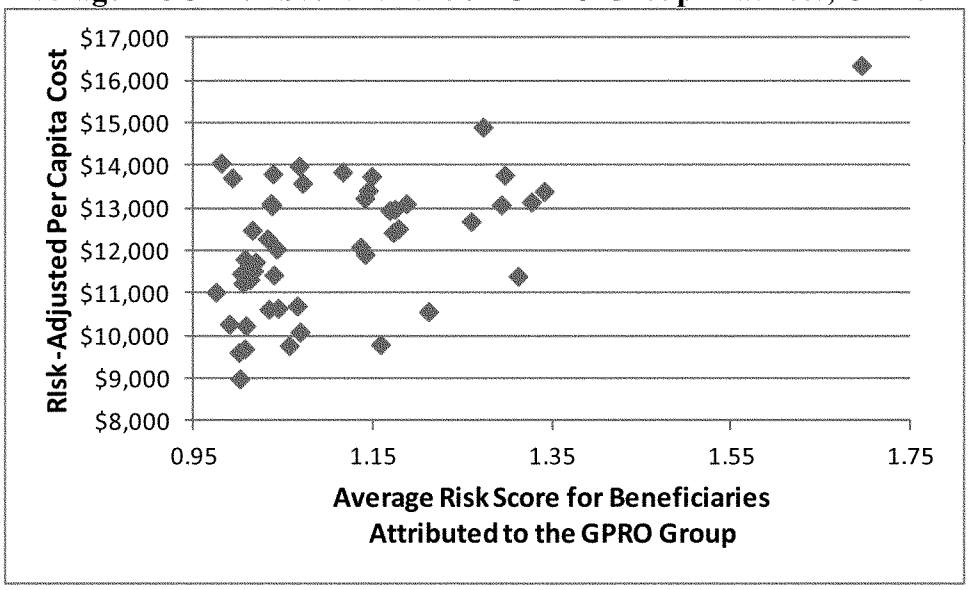
In December 2012, we produced and distributed QRURs to each of the 54 medical group practices that chose to participate in the CY 2011 GPRO under the PQRS. Each report provided information on 30 quality measures and five resource use (cost) measures for Medicare FFS beneficiaries treated by the medical groups in CY 2011. For each of the five cost measures, we standardized the input costs to adjust for differences in Medicare payments geographically and various Medicare payment policies such as Indirect Graduate Medical Education and Disproportionate Share Hospital add-on payments. We also risk adjusted the cost measures based on the unique mix of patients attributed to the physician or group of physicians. Costs for beneficiaries with high risk factors (such as a history of chronic diseases, disability, or increased age) are adjusted downward, and costs for beneficiaries with low risk factors are adjusted upward. More information on the payment standardization and risk adjustment techniques is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/downloads/2011_group_detail_methodology.pdf.*

To participate in the PQRS GPRO in CY 2011, a group practice had to be a single provider entity, as identified by its TIN, with at least 200 eligible professionals. Fifty-four groups, encompassing 37,745 eligible professionals, participated in the 2011 PQRS GPRO. On average the group contained the following type of medical professionals: Primary care physicians (22 percent); medical specialists (22 percent); surgeons (16 percent); emergency medicine physicians (4 percent); other physicians (13 percent); and other medical professionals (23 percent).

For each of the 54 GPRO practices, we attributed a Medicare FFS beneficiary to the group if eligible professionals in the group billed for at least two of the beneficiary's eligible office visits or other outpatient evaluation and management (E&M) services provided in CY 2011 and the group practice had the plurality of CY 2011 E&M allowed charges for that beneficiary. The average beneficiary population attributed to a group practice was 12,764 beneficiaries, with the smallest group practice attributed 808 beneficiaries and the largest attributed 33,907 beneficiaries. Highlights of major findings from these 2011 QRURs are as follows:

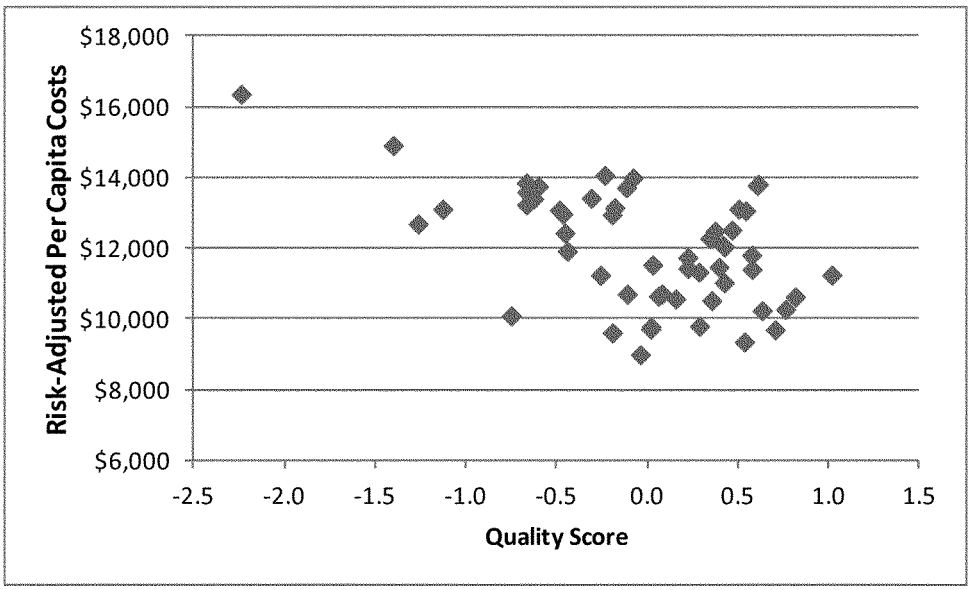
- The mean group practice performance rate on each PQRS quality measures was equal to, or better than the individual physician reported performance rate for 13 of 22 comparable quality measures (60 percent), but lower for the other 9 measures.
- Although there is a positive correlation (0.59), risk-adjusted total per capita costs for each group are fairly dispersed at any given level of risk (Table 67).

TABLE 67: Relationship Between Risk-Adjusted Total Per Capita Costs and Average HCC Risk Score for the 54 GPRO Group Practices, CY 2011



• We also constructed a quality composite score for each of the 54 groups by combining the 26 clinical quality measures, the chronic conditions ACSC composite [9] and acute conditions ACSC composite, and the two hospital discharge measures. Table 68 displays the relationship between the composite quality score for each group practice and the total payment-standardized risk-adjusted per capita cost measure. Although there is a negative correlation (−0.53), total per capita costs are fairly dispersed at any given level of quality.

TABLE 68: Quality of Care Compared to Cost, CY 2011



The performance rates for the 54 groups on the quality of care and cost measures were statistically reliable at a high level across the vast majority of the measures. More information about findings from these reports is available at *http://www.cms.hhs.gov/physicianfeedbackprogram.html.*

b. Individual Physician Feedback Reports Based on CY 2011 Data and Disseminated in CY 2012.

In December 2012, we provided individual 2011 Quality and Resource Use Reports to over 94,000 physicians

[9] The chronic conditions composite was constructed as the sum of the numerators for diabetes, COPD, and heart failure ACSC measures divided by the sum of their corresponding denominators.

affiliated with medical group practices of 25 or more eligible professionals (that is, these group practices include physicians and other medical staff such as nurse practitioners and physician assistants). The physician groups were based in 9 states: California; Illinois; Iowa; Kansas; Michigan; Minnesota; Missouri; Nebraska; and Wisconsin. Over the 4-month period during which reports were available, 31,518 individual reports were downloaded.

The QRURs contained performance on PQRS measures for physicians who participated in the CY 2011 program. They also contained performance information on 28 quality indicators for preventive care, medication management, and eight separate condition categories, such as chronic obstructive pulmonary disease (COPD) and cancer. We calculated rates for these measures using CY 2010 and CY 2011 Medicare administrative claims. Of these 28 measures, 14 measures will be included in the PQRS Administrative Claims reporting mechanism available for groups of physicians and individual EPs in CY 2013.

The QRURs also provided measures of physician resource use. These measures were payment-standardized and risk-adjusted total Parts A and B per capita costs for beneficiaries treated by the physician. Payment standardization adjusts for differences in Medicare payment rates to compare service use within or across geographic regions. Risk adjustment accounts for differences in costs among physician that result from variation in patient mix. We included five measures of cost in the QRURs: total per capita costs for all beneficiaries attributed to the physician and total per capita costs for attributed beneficiaries with one of four chronic conditions (diabetes, heart failure, COPD, or coronary artery disease (CAD)). For the cost measures, we attribute beneficiaries to physicians based on each physician's degree of involvement with the beneficiary. The three categories of attribution are directed, influenced, and contributed, which are based on the percentage of each beneficiary's evaluation and management services or total professional costs. More information about the methodologies used in the CY 2011 Individual QRURs is available at *http://www.cms.hhs.gov/physicianfeedbackprogram*.

The following is a summary of the highlights from these reports:

- Among high-risk Medicare beneficiaries, visiting a primary care physician during the year was associated with lower costs, but having a physician who is more involved in one's care (that is, the physician directed or influenced care) is associated with the lowest costs, on average. For this analysis a physician directed or influenced care if the physician billed for 35 percent or more of the patient's office or other outpatient E&M visits or for 20 percent or more of the patient's total professional costs.
- The average reliability score was high (greater than 0.70) for 98 percent (125) of the 128 PQRS measures reported by physicians in the nine states with a case size of at least 20. A total of 109 of the 128 measures (85 percent) had average reliabilities greater than 0.90. These reliability scores were substantially higher than for the 14 measures that are included in the CY 2013 PQRS Administrative Claims reporting mechanism. Reliability scores range from zero to one and measure the extent to which the performance of one physician can be confidently distinguished from another.
- The performance rate for at least 25 percent of physicians was significantly different from the mean for 5 of the 10 most reported PQRS measures in the 9 states. However, none of the 14 Administrative Claims-based measures had performance rates that were significantly different from the mean for at least 25 percent of physicians. These results suggest statistically significant variation across physicians is more likely to be detected using the most common self-reported PQRS quality measures rather than the Administrative Claims measures.
- Across the 9 states, the average of the total per capita cost (payment-standardized and risk-adjusted) among physicians was $18,735. Among total per capita costs for beneficiaries with the four chronic condition, total per capita costs for heart failure were highest ($34,545), followed by COPD ($32,946), CAD ($25,906), and diabetes ($25,016).
- Across the 9 states, the average reliability for physicians' total per capita costs was very high at 0.97, when a physician had at least 20 cases. The average reliability of the total per capita cost measure (among physicians with 20+ cases) for directed patients was 0.85, for influenced patients was 0.71, and for contributed patients was 0.97. These results demonstrate that for the typical physician profiled with a minimum case size of 20 the overall per capita cost measure is reliable.

More information about the aggregate findings from these reports is also available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ReportTemplate.html*.

c. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A)(ii) of the Act, as added by section 3003 of the Affordable Care Act, requires CMS to develop a Medicare episode grouper by January 1, 2012, and to 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 is software that organizes claims data into episodes. We have developed a CMS prototype episode grouper that, for a limited number of conditions, classifies episodes into three categories: chronic; acute; and procedural.

To illustrate how the CMS Episode Grouper works, in June 2013 we developed supplemental QRURs and made them available to the 54 large group practices that we had provided group QRURs in December 2012. The CY 2011 Supplemental Episode Grouper QRURs included the following five major episodes along with seven episode sub-types that further stratified the episode:

- Pneumonia (acute condition).
  - ++ With (inpatient) hospital stay.
  - ++ Without hospital stay.
- Acute Myocardial Infarction (AMI) (acute condition).
  - ++ Without Percutaneous Coronary Interventions (PCI) or Coronary Artery Bypass Graft (CABG).
  - ++ With PCI.
  - ++ With CABG.
- Coronary Artery Disease (CAD) (chronic condition).
  - ++ Without AMI.
  - ++ With AMI.
- CABG (without AMI) (procedural).
- PCI (without AMI) (procedural).

The Supplemental QRURs assign, or attribute, responsibility for the patient's care for each episode to a medical practice group. Episode assignment to medical practice groups for the Supplemental QRURs was based on one or more of the following three methods, depending upon the episode type:

- The performance of specific procedures.
- The plurality (35 percent) of episode EP fee schedule (PFS) costs billed.
- The plurality or shared majority (35 percent) of E&M visits.

Each of these methods relies on different criteria to attribute episodes to groups. We used the first method when a single procedure, such as a surgery, triggers, or begins, an episode of care. In this case, the group performing the

surgery is assumed to be responsible for the care. We used this method to attribute PCI and CABG episode types to group practices.

The latter two methods attribute the episode based on EPs' relative billing made during the episode. Attribution using PFS costs assumes that certain types of EPs who are paid higher amounts during the episode are likely to have interacted most with the patient and directed the patient's care. The PFS cost attribution method excludes costs from laboratories and ambulances, as well as other settings to reduce the likelihood that non-clinicians, are attributed the episode. Use of E&M visit attribution assumes that EPs who most frequently visit the beneficiary during the episode are likely to have substantial responsibility for the services rendered during the episode. The chronic CAD episode type used only E&M visits for attribution, while the acute AMI and pneumonia episodes used both PFS costs and E&M visits. More information about the group attribution methodologies is available at: *www.cms.gov/physicianfeedback program*.

To control for patient case-mix, the CMS Episode Grouper applied a risk-adjustment methodology. The risk-adjustment methodology calculated each episode's expected cost based on three factors: patient health status; demographics; and beneficiary type. Using these factors, the risk-adjustment model calculated the predicted cost of an episode using information available at the start of the episode.[10] 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. The risk-adjusted cost amount was defined to be equal to the average episode cost nationally plus the difference between the episode cost level and the predicted cost level derived from the risk-adjustment model. All cost figures used in the risk-adjustment model are payment-standardized.

To make the Supplemental QRURs more actionable for medical groups for quality improvement and care coordination, the Supplemental QRURs identify a suggested individual provider within the group who is likely to be directing the care during the episode. This individual is designated as the ''Suggested Lead Eligible Professional (EP)'' of the episode. In addition 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. More information about the Supplemental QRURs is available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html*.

We view these Supplemental QRURs as the beginning of an extended process of incorporating episode costs into the QRURs. We intend to develop the CMS Episode Grouper (based in the CMS' Center for Medicare and Medicaid Innovation) and to broaden the number of conditions that could be addressed by episode grouping. The feedback that CMS expects from the 54 medical practice groups report recipients will inform next steps.

d. Future Plans for the Physician Feedback Reports

In September, 2013, we plan to provide the QRURs at the TIN level to all groups of physicians with 25 or more eligible professionals. The QRURs will be based on CY 2012 performance data. We anticipate that there will be approximately 6,750 reports (including 1,235 groups of 100 or more EPs) covering approximately 440,000 physicians. These reports will include a ''first look'' at the value-based payment modifier methodologies using the group's PQRS measures, outcome measures, and cost measures.

The reports also incorporate many valuable suggestions we have received from specialty societies and professional societies on ways to make these reports more meaningful and actionable. In particular, the reports will contain details regarding: (1) Beneficiaries attributed to the group practice (for example, beneficiary identifying information, information regarding services furnished by the group to the beneficiary, risk score percentile, last hospital admission, and chronic conditions); (2) Physicians and non-physician eligible professionals billing under the group's TIN; and (3) Hospitalizations for attributed beneficiaries to help each group manage its patients and potentially reduce hospital admissions (including, for example, (a) beneficiary identifying information, (b) hospital admission data such as data of admission, admitting hospital, principal diagnosis, and (c) discharge disposition information). We plan to provide this additional information to support the group's quality improvement and care coordination efforts. As part of its review of these detailed reports, each group will also be able to compare the data in the reports with its own records (for example, professionals billing under the group's TIN) to verify the information in the CMS reports. We note that these reports are developed following a 90-day claim run-out, meaning that claims for services furnished during CY 2012 are included in the reports if the claim was paid by March 31, 2013.

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 representing physicians in anesthesiology, cardiology, cardiothoracic surgery, emergency medicine, neurosurgery, pathology, and radiology 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 value-based payment modifier would apply to the group of physicians, but to provide these 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 of physicians with fewer than 100 eligible professionals will not be subject to the value-based payment modifier in CY 2015. 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.

We continue to look at ways to streamline the QRURs supporting the PQRS and the physician value-based payment modifier programs in order to create one unified format for quality assessment to increase their utility in future years.

L. Updating Existing Standards for E-Prescribing Under Medicare Part D

1. Background

a. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Act. Among other things,

[10] CAD episodes are risk-adjusted each quarter, and the data used for risk adjustment is updated with each new quarter.

these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

(1) Foundation and Final Standards

CMS utilized several rounds of rulemaking to adopt standards for the e-prescribing program. Its first rule, which was published on November 7, 2005 (70 FR 67568), adopted three standards that were collectively referred to as the ''foundation'' standards. We issued a subsequent rule on April 7, 2008 (73 FR 18918) that adopted additional standards which are referred to as ''final'' standards. One of these standards, the NCPDP Formulary and Benefit Standard, Implementation Guide, Version 1, Release 0 (Version 1.0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) was a subject of the calendar year (CY) 2013 Physician Fee Schedule (PFS) final rule with comment period (77 FR 68892 at 69329) and is the subject of this proposed rule. Please see the ''Initial Standards Versus Final Standards'' discussion at 70 FR 67568 in the November 7, 2005 rule for a more detailed discussion about ''foundation'' and ''final'' standards.

(2) Updating e-Prescribing Standards

As noted previously, transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in its November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ''updating process'' when a standard could be updated with a newer ''backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**.

(3) The NCPDP Formulary and Benefit Standard in the Part D e-Prescribing Regulations

The backward compatibility concept has been used extensively to update the NCPDP SCRIPT standard in the Part D e-prescribing program, but it has not yet been used to update the adopted NCPDP Formulary and Benefit Standard. We proposed to update the NCPDP Formulary and Benefit 1.0 standard for the first time in the CY 2013 PFS proposed rule (77 FR 44722), but we did not ultimately finalize those proposals. Specifically, we proposed to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits 1.0 effective 60 days from the publication of the final rule, and sought comment on when we should retire NCPDP Formulary and Benefits 1.0 as well as when we should adopt NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard. As was noted in that rule, while recognition of backward compatible versions can be done in an interim final rule in which we waive notice and comment rulemaking, other Part D e-prescribing proposals that were being made at that time required full notice and comment rulemaking, so, as we didn't wish to publish two e-prescribing rules contemporaneously, we elected to forgo our usual use of our simplified updating process for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through full notice and comment rulemaking.

2. Proposals

a. Proposed Backward Compatible Standards

As was discussed in the CY 2013 PFS final rule with comment period (77 FR 68892), we were persuaded by commenters to refrain from retiring Formulary and Benefit Standard 1.0 until NCPDP ceased supporting it on July 1, 2014. As further noted in that rule, we believed it best to delay implementing any of our Formulary and Benefits proposals, including recognitions of NCPDP Formulary and Benefit 3.0 as a backward compatible standard, until closer to that July 1, 2014 date. Our actions at that time were based on a belief that an extended period of use of either 3.0 or 1.0 would be ill-advised.

Having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believe that it is now appropriate to re-propose the recognition of NCPDP Formulary and Benefits 3.0 as a backward compatible version of Formulary and Benefits 1.0 effective 60 days after publication of a final rule until June 30, 2014, and, as discussed below, to propose the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and to propose the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard effective July 1, 2014. As was discussed previously, while the recognition of backward compatible standards can be done in an interim final rule in which we waive notice and comment rulemaking, in light of other Part D e-prescribing proposals being made in this rule that require full notice and comment rulemaking, we will forgo use of the simplified updating method for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through a single notice and comment rulemaking.

Also, as was seen in our prior proposal to recognize backward compatibility using full notice and comment in place of the backward compatible methodology, we must also propose to require users of 3.0 to support users who are still using NCPDP Formulary and Benefit 1.0 until such time as that version is officially retired as a Part D e-prescribing standard and NCPDP Formulary and Benefit 3.0 is adopted as the official Part D e-prescribing standard.

2. Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and adoption of NCPDP Formulary and Benefit Standard 3.0

As noted in the CY 2013 PFS proposed rule, the NCPDP Formulary and Benefits standard provides a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

Also as noted in that proposed rule, standards are updated over time to take industry feedback and new and modified business needs into account. See the CY 2013 PFS proposed rule (77 FR 45023–45024) for a full discussion of the changes to that were made to the NCPDP Formulary and Benefit 1.0 as it was updated to the NCPDP Formulary and Benefit 3.0.

As noted above, having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believe that it is now appropriate to re-propose the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and to propose the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard, effective July 1, 2014.

To effectuate these proposals, we propose to revise § 423.160(b)(5). We propose to place the existing material in a new paragraph (b)(5)(i), which would provide the formulary and benefit standard for Part D e-prescribing until [60 days after publication of the final rule]. We then propose to create a second new paragraph ((b)(5)(ii)) to recognize NCPDP Formulary and Benefit 3.0. as a backward compatible version of the official Part D e-prescribing standard (NCPDP Formulary and Benefit 1.0), effective [60 days after publication of the final rule] through June 30, 2014. Furthermore, we propose to create a third new paragraph ((b)(5)(iii)) to reflect the retirement of NCPDP Formulary and Benefit 1.0 and the adoption of NCPDP Formulary and Benefit 3.0 as the official Part D e-prescribing standard, effective July 1, 2014. Finally, we propose to make conforming changes to § 423.160(b)(1). We seek comment on these proposals.

M. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage for chiropractic services is limited to treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act provided such treatment is legal in the state or jurisdiction where performed. The demonstration expanded Medicare coverage to include: ''(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the state or jurisdiction in which such treatment is provided.'' The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that ''the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.''

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate BN. In the ''All Neuromusculoskeletal Analysis,'' which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was $114 million higher costs for beneficiaries in areas that participated in the demonstration. In the ''Chiropractic User Analysis,'' which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a $50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup $50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping $10 million for each such year through adjustments to the

chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

For the CY 2013 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately $470 million, which reflected the statutory 26.5 percent reduction to PFS payments scheduled to take effect that year. The statute was subsequently amended to impose a zero percent PFS update for CY 2013 instead of the 26.5 percent reduction. In large part because of the change in the PFS update, OACT now estimates CY 2013 chiropractic expenditures to be approximately $580 million. Because of the change in projected chiropractic expenditures, we now expect to recoup approximately $11.6 million from the 2 percent payment reduction for chiropractic CPT codes in CY 2013.

We expect to complete the required BN adjustment by recouping the remainder of the chiropractic expenditures in CY 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. While OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: $540 million in 2010; $520 million in 2011; and $580 million in 2012. In total, CMS recouped $32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately $580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately $11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately $44.4 million of the $50 million required for budget neutrality.

In 2014, CMS is reducing the recoupment percentage for the chiropractic codes to ensure the recoupment does not exceed the $50 million required for budget neutrality. OACT estimates chiropractic expenditures in CY 2014 will be approximately $480 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 25 percent reduction to physician payments scheduled to take effect under current law. CMS plans to recoup the remaining funds, approximately $5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage, which by our preliminary estimates is one percent which takes into account the approximately 25 percent reduction in physician payments scheduled to occur in 2014 as provided under current law. If the statute is amended to avoid the physician payment reduction, we will reduce the recoupment percentage as appropriate to ensure the recoupment does not exceed $50 million. For instance, if the statute is amended to provide for a zero percent PFS update, we would reduce the recoupment percentage to approximately 0.7 percent. We will reflect this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the RVUs. Avoiding an adjustment to the RVUs preserves the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

Therefore, as finalized in the CY 2010 PFS regulation and reiterated in the CYs 2011 through 2013 PFS regulations, we are implementing this methodology and recouping excess expenditures under the chiropractic services demonstration from PFS payment for the chiropractor codes as set forth above. This recoupment addresses the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration. We intend for CY 2014 to be the last year of this required recoupment.

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. In order 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

1. ICRs Regarding Medical Services Coverage Decisions That Relate to Health Care Technology (§ 405.211)

The burden associated with the requirements under § 405.211 is the time and effort it would take a study sponsor that is requesting Medicare coverage of an FDA-approved IDE to prepare the following as electronic documents: (1) A copy of the FDA IDE approval letter; (2) a copy of the IDE study protocol; (3) a copy of IRB approval letter(s); and (4) the *ClinicalTrails.gov* identifier. CMS reviews these documents to determine whether it should cover certain costs in an IDE trial or study.

Each IDE trial sponsor will have to prepare these documents once. If the sponsor requests a second review, the documents will have to be sent again. We estimate that this may happen 5–8 percent of the time. Since the IDE rule was passed in September 1995 through 2012, there have been 4,000 IDE applications, averaging 222 per year. Adding another 8 percent brings the total estimate of about 240 requests per year.

The study sponsors do not have to create new documents. Rather they will be required to send us copies of information they have sent to the FDA and that the FDA has sent to them. Accordingly, we estimate that it will take 1 hour for an executive administrative assistant in a medical device company to prepare: (1) A copy of the FDA IDE approval letter; (2) a copy of the IDE study protocol; (3) a copy of IRB approval letter(s); and (4) the ClinicalTrails.gov identifier, for electronic submission.

We estimate that for 240 requests per year, that the total estimated cost to the public is $7,821 annually. In deriving these figures, we used the Bureau of Labor Statistics May 2012 estimate of $24.14 + 35 percent in fringe benefits for estimated hourly wage of $32.59 for an executive administrative assistant (occupation code 43–6011).

2. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

We are making certain revisions to § 414.90, primarily to include our proposals for the qualified clinical data registry option. All of the requirements

and burden estimates are currently approved by OMB under OCN 0938–1059, and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

We are revising § 414.90(b), (c), and (e) to indicate our proposals for the qualified clinical data registry option. While the sections contain information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions.

The preamble of this proposed rule discusses the background of the PQRS, provides information about the measures and reporting mechanisms that would be available to eligible professionals and group practices who choose to participate in 2014, and provides the proposed criteria for satisfactory reporting in 2014 (for the 2014 PQRS incentive and the 2016 PQRS payment adjustment). Below are our burden estimates for participating in the PQRS in 2014 which are subject to OMB review/approval under OCN 0938–1059.

a. Participation in the 2013 and 2014 PQRS

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are proposing additional proposals, this section modifies the impact statement provided in the CY 2013 PFS final rule with comment period for reporting in 2014. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter ''the PQRS Reporting Experience''). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/*. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27% of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 is accurate.

With respect to the estimated amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (i.e., a bonus payment equal to 0.5 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting, a reduction of 1.0 percent from 2011. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27% of 1 million eligible professionals) 270,000 eligible professionals. At $1,059 per eligible professional, the PQRS would distribute approximately $286 million in incentive payments in 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- The proposals for reporting for the PQRS for the 2014 incentive and 2016 payment adjustment would be established as proposed in this CY 2014 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would attempt to report PQRS quality measures data with the intention of earning the 2014 PQRS incentive. Therefore, an eligible professional or group practice would report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

Please note that these estimates do not reflect total costs estimates for participating in PQRS, but rather cost estimates that would change if our proposals are finalized.

b. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS—New Individual Eligible Professionals: Preparation

For an eligible professional who wishes to participate in PQRS as an individual, the eligible professional need not indicate his/her intent to participate. Instead, the eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in PQRS would be approximately $80 ($16/hour × 5 hours).

c. Burden Estimate on Participation in the 2013 and 2014 PQRS via the Claims-Based Reporting Mechanism—Individual Eligible Professionals

Historically, the claims-based reporting mechanism is the most widely used reporting mechanism in PQRS. In 2011, 229,282 of the 320,422 eligible professionals (or 72 percent of eligible professionals) used the claims-based reporting mechanism. In the CY 2013 PFS final rule with comment period, we estimated that approximately 320,000 eligible professionals, whether participating individually or in a group practice, would participate in PQRS by CY 2014 (77 FR 69338). We believe this estimate should be further modified to reflect a lower participation estimate in 2014 due to the following proposals:

- We are proposing to eliminate the option to report measures groups via claims for the 2014 PQRS incentive.

• We are proposing to increase the number of measures that an eligible professional must report to meet the criteria for satisfactory reporting for the 2014 PQRS incentive from 3 measures to 9, but lower the reporting threshold to 50%.

• We are proposing to remove the claims-based reporting mechanism as an option for reporting certain individual quality measures.

Based on these proposals, we estimate that approximately 230,000 eligible professionals (that is, the same number of eligible professionals who participated in the PQRS using the claims-based reporting mechanism in 2011) will participate in the PQRS using the claims-based reporting mechanism. Therefore, we estimate that approximately 58 percent of the eligible professionals participating in PQRS will use the claims-based reporting mechanism.

With respect to an eligible professional who participated in PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submitted for payment. PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims would range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. Using an average labor cost of $40/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from $1.50 (2.25 minutes or 0.0375 hours × $40/hour) to $72.00 (108 minutes or 1.8 hours × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we established that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which eligible professional reports would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent for claims-based reporting, we found that the median number of reporting cases for each measure was 9. Since we reduced the reporting threshold to 50 percent, we estimated that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimated that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($1.50/per reported case × 6 reported cases) $9.00 to ($72.00/reported case × 6 reported cases) $432.

d. Burden Estimate on PQRS Participation in CY 2014 via the Qualified Registry, Qualified Clinical Data Registry, or EHR Reporting Mechanisms

We noted previously that we estimate a significant reduction in the number of eligible professionals using the claims-based reporting mechanism to report PQRS quality measures data in 2014. Specifically, we estimate that approximately 230,000 eligible professionals will participate in the PQRS using the claims-based reporting mechanism in 2014. Therefore, we estimate that the remainder of the eligible professionals (170,000) will participate in PQRS using either the qualified registry, qualified clinical data registry, EHR (using either a direct EHR or EHR data submission vendor), or the GPRO web interface reporting mechanisms.

With respect to participation in a qualified registry or qualified clinical data registry, we are combining our estimates for the number of eligible professionals we believe will use the qualified registry and qualified clinical data registry reporting mechanisms for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We are combining these estimates because we believe that, at least for this initial year, many of the registries that become qualified clinical data registries will also be existing qualified registries. As such, we anticipate there will be little to no additional registries that will submit quality measures data to the PQRS for purposes of the 2014 PQRS incentive and 2016 PQRS payment adjustment.

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using a qualified registry or qualified clinical data registry would remain the same, as eligible professionals use registries for functions other than PQRS and therefore would obtain a qualified registry or qualified clinical data registry solely for PQRS reporting by CY 2014. Please note that this estimate would include participants choosing the newly proposed qualified clinical data registry reporting mechanism. At least in its initial stage, we believe most of the vendors that would be approved to be a qualified clinical data registry would be existing qualified registries.

In 2011, 560 (or less than 1%) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism would increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals and group practices would transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 50,000 eligible professionals (which is the same estimate as we are providing for eligible professionals who use the qualified registry or qualified clinical data registry-based reporting mechanisms), whether participating as an individual or part of a group practice, would use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participated in PQRS via a qualified registry, qualified clinical data registry, direct EHR product, or EHR data submission vendor's product, we believe there would be little to no burden associated for an eligible professional to report PQRS quality measures data to CMS, because the selected reporting mechanism submitted the quality measures data for the eligible professional. While we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, qualified clinical data registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, or EHR data submission vendor product in our burden estimates.

e. Burden Estimate on PQRS Participation in CY 2014—Group Practices

Please note that with the exception of the estimates associated with a group self-nominating to participate in the PQRS under the GPRO, this section only contains our estimates for group

practices who participate in the PQRS under the GPRO via the GPRO web interface reporting mechanism. We note that the burden associated with reporting quality measures for group practices using the qualified registry or EHR-based reporting mechanisms are included in the estimates we provided for the qualified registry or EHR-based reporting mechanisms above. According to the PQRS and eRx Experience report, of the 101 practices participating in the GPRO, 54 of these practices participated using the GPRO web interface (formerly the GPRO tool). We estimate that because we are proposing to apply the value-based payment modifier to all group practices of 10 or more eligible professionals, we estimate that approximately 30% of such group practices, or about 5,100 group practices, will participate in the PQRS under the GPRO for purposes of the 2014 PQRS incentive and the 2016 payment adjustment. In addition, we estimate that of the 5,100 group practices that are expected to self-nominate to participate in the PQRS under the GPRO, approximately 70,000 eligible professionals (i.e. the remainder of the eligible professionals not participating in PQRS using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms), representing about 30% of the groups with 100 or more eligible professionals (or about 340 groups), will choose to participate in PQRS using the GPRO web interface for purposes of the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

Unlike eligible professionals who choose to report individually, we noted that we proposed that eligible professionals choosing to participate as part of a group practice under the GPRO would need to indicate their intent to participate in PQRS as a GPRO. The total burden for group practices who submit PQRS quality measures data via the GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in PQRS as a GPRO; 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96.

With respect to reporting PQRS quality measures using the GPRO web-interface, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS quality measures data for an applicable year would be ($40/hour × 79 hours) $3,160.

In addition to the GPRO web interface, please note that we have proposed a new reporting mechanism that would be available to group practices comprised of 25+ eligible professionals: the certified survey vendor. With respect to using a certified survey vendor, we believe there would be little to no burden associated for a group practice to report the CG CAHPS survey data to CMS, because the selected reporting mechanism submitted the quality measures data for the group practice. While there may be start-up costs associated with purchasing a certified survey vendor, we believe that a group practice would not purchase a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of purchasing a certified survey vendor in our burden estimates.

f. Burden Estimate on PQRS Vendor Participation in CY 2014

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that entities that wish to become qualified clinical data registries would incur costs associated with participating in PQRS. However, we believe that the burden associated with participating in PQRS for these entities would be very similar to the burden associated with existing qualified registries participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimated that approximately 50 additional registries would self-nominate to be considered a qualified registry for PQRS. With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries and qualified clinical data registries who submitted PQRS quality measures data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed PQRS program years, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimated that it would take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wished to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimate that it would cost a registry approximately ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in PQRS. Therefore, we believe there is little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden would vary with each registry, depending on the registry's level of savvy with submitting quality measures data for PQRS.

For CY 2014, we are proposing a new PQRS option that includes a new reporting mechanism—the qualified clinical data registry. In this proposed rule, we set forth the requirements for a vendor to become qualified to become a qualified clinical data registry. Under the proposed requirements, we note that a vendor can be both a traditional qualified registry and qualified clinical data registry under the PQRS. Indeed, as we noted previously, we believe that many of the entities that will seek to become qualified clinical data registries will be similar to the existing qualified registries. In addition, at least initially, we propose that the process for becoming a qualified clinical data registry would be similar to the process for becoming a qualified registry. Therefore, we do not believe this new

reporting mechanism will impact our registry estimates.

h. Summary of Burden Estimates on Participation in the 2013 and 2014 PQRS—Eligible Professionals and Vendors

TABLE 69—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Hours	Cases	Number of measures	Hourly rate	Cost per respondent	Number of respondents	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80	320,422	$32,000,000
Individual EP: Claims	0.2	6	3	$40	$144	230,000	$33,120,000
Individual EP: Registry	N/A	1	N/A	N/A	Minimal	40,422	[1] N/A
Individual EP: EHR	N/A	1	N/A	N/A	Minimal	50,000	[1] N/A
Group Practice: Self-Nomination	6.0	1	N/A	$16	$96	5,100	$489,600
Group Practice: Reporting	79	1	N/A	$40	$3,160	340	$1,074,400

[1] We believe that eligible professionals who choose to report quality measures data to PQRS using a registry, an EHR, or an EHR data submission vendor are already doing so for other purposes. Therefore, there would be little to no burden associated with reporting the quality data to CMS under PQRS.

TABLE 70—ESTIMATED COSTS TO REGISTRIES TO PARTICIPATE IN PQRS

	Hours	Hourly rate	Cost	Number of respondents	Total cost
Registry: Self-Nomination	10	$16	$160	50	$8,000

3. The Medicare EHR Incentive Program

The Medicare EHR Incentive Program provides incentive payments to eligible professionals, eligible hospitals, and CAHs that demonstrate meaningful use of certified EHR technology. We believe any burden or impact associated with our proposals regarding the EHR Incentive Program is already absorbed by the currently approved (OCN 0938–1158) burden and impact estimates provided the EHR Incentive Program. Consequently, the proposed requirements (and burden) are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

4. Submission of PRA-Related Comments

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–1590–FC]

Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

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 considered all comments we received by the date and time specified in the **DATES** section of this preamble, and, when we proceeded with a subsequent document, we responded 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 Affordable Care Act (Pub. L. 111–148), the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), the American Taxpayer Relief Act (ATRA) of 2013 (Pub. L. 112–240), and other statutory changes. This proposed rule also is necessary to make changes to 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 and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million in any 1 year (for details see the SBA's Web site at *http://www.sba.gov/content/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.

For purposes of the RFA, physicians, NPPs, and suppliers are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of providers and suppliers are considered to be small entities. 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 2013, that threshold is approximately $141 million. This proposed rule will 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. Relative Value Unit (RVU) Impacts

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

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

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2013 with proposed payment rates for CY 2014 using CY 2012 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

We note that these impacts do not include the effect of the January 2014 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or ''target'' expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the ''SGR'' methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with sections 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. 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 reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. We provide our most recent estimate of the SGR and physician update for CY 2014 on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/*.

Tables 71 and 72 show the payment impact on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different from those shown in Tables 71 (CY 2014 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty) and 72 (CY 2014 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty by Selected Proposal).

The following is an explanation of the information represented in Table 71:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.

• *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 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 and Malpractice (MP) RVU Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the work and malpractice 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 changes in the PE RVUs.

• *Column E (Combined Impact):* This column shows the estimated CY 2014 combined impact on total allowed charges of all the changes in the previous columns.

TABLE 71—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty	Allowed charges (mil)	Impact of work and MP RVU changes (percent)	Impact of PE RVU changes (percent)	Combined impact (percent)
(A)	(B)	(C)	(D)	(E)
TOTAL	$86,995	2	−2	0
01—ALLERGY/IMMUNOLOGY	213	1	−4	−3
02—ANESTHESIOLOGY	1,862	4	−1	3
03—CARDIAC SURGERY	355	3	−1	2
04—CARDIOLOGY	6,425	2	0	2
05—COLON AND RECTAL SURGERY	158	2	−2	0
06—CRITICAL CARE	273	3	−1	2
07—DERMATOLOGY	3,113	2	−4	−2
08—EMERGENCY MEDICINE	2,929	3	0	3
09—ENDOCRINOLOGY	447	2	−2	0
10—FAMILY PRACTICE	6,358	2	−1	1
11—GASTROENTEROLOGY	1,901	3	−2	1
12—GENERAL PRACTICE	528	2	−2	0
13—GENERAL SURGERY	2,236	3	−2	1
14—GERIATRICS	231	3	−1	2
15—HAND SURGERY	151	2	−2	0
16—HEMATOLOGY/ONCOLOGY	1,890	2	−3	−1
17—INFECTIOUS DISEASE	635	3	−1	2
18—INTERNAL MEDICINE	11,416	3	−2	1
19—INTERVENTIONAL PAIN MGMT	640	2	−3	−1
20—INTERVENTIONAL RADIOLOGY	219	2	−6	−4
21—MULTISPECIALTY CLINIC/OTHER PHY	79	2	−2	0
22—NEPHROLOGY	2,123	3	−2	1
23—NEUROLOGY	1,498	2	−4	−2
24—NEUROSURGERY	712	2	−1	1
25—NUCLEAR MEDICINE	51	2	−1	1
27—OBSTETRICS/GYNECOLOGY	688	2	−2	0
28—OPHTHALMOLOGY	5,592	2	−2	0
29—ORTHOPEDIC SURGERY	3,683	2	−2	0
30—OTOLARNGOLOGY	1,128	2	−4	−2
31—PATHOLOGY	1,134	3	−8	−5
32—PEDIATRICS	63	3	−3	0
33—PHYSICAL MEDICINE	999	3	−3	0
34—PLASTIC SURGERY	367	2	−2	0
35—PSYCHIATRY	1,165	3	−1	2
36—PULMONARY DISEASE	1,775	3	−2	1
37—RADIATION ONCOLOGY	1,783	1	−6	−5
38—RADIOLOGY	4,635	2	−3	−1
39—RHEUMATOLOGY	551	2	−5	−3
40—THORACIC SURGERY	332	3	−1	2
41—UROLOGY	1,858	2	−4	−2
42—VASCULAR SURGERY	925	2	−4	−2
43—AUDIOLOGIST	56	2	−1	1
44—CHIROPRACTOR	722	3	−1	2
45—CLINICAL PSYCHOLOGIST	579	4	−1	3
46—CLINICAL SOCIAL WORKER	408	4	−1	3
47—DIAGNOSTIC TESTING FACILITY	779	0	−7	−7
48—INDEPENDENT LABORATORY **	812	1	−27	−26
49—NURSE ANES/ANES ASST	1,055	4	0	4
50—NURSE PRACTITIONER	1,937	3	−2	1
51—OPTOMETRY	1,106	2	−2	0
52—ORAL/MAXILLOFACIAL SURGERY	44	2	−4	−2
53—PHYSICAL/OCCUPATIONAL THERAPY	2,797	2	−1	1
54—PHYSICIAN ASSISTANT	1,405	3	−2	1
55—PODIATRY	1,975	2	−2	0
56—PORTABLE X-RAY SUPPLIER	110	1	−2	−1

TABLE 71—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty	Allowed charges (mil)	Impact of work and MP RVU changes (percent)	Impact of PE RVU changes (percent)	Combined impact (percent)
(A)	(B)	(C)	(D)	(E)
57—RADIATION THERAPY CENTERS	62	0	−13	−13
98—OTHER	25	3	−2	1

* Table 71 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the January 2014 conversion factor change required under current law.
** PFS Payments only, which account for ~17% of Independent Laboratory payments from Medicare.

Table 72 shows the estimated impact of selected policy proposals on total allowed charges, by specialty. The following is an explanation of the information represented in Table 72:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 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 2012 Claims data, 90 Percent Equipment Utilization Assumption, Ultrasound Changes, and Other Minor Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the RVUs due to the 90 percent equipment utilization assumption discussed in section II.A.2.f. of this proposed rule, ultrasound changes discussed in section II.A.5, the use of CY 2012 claims data to model payment rates, and all other proposals that result in minimal redistribution of payments under the PFS.
- *Column D (Impact of OPPS/ASC cap):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the RVUs resulting from our proposed policy discussed in section II.A.4. of this proposed rule.
- *Column E (Impact of MEI Revision):* This column shows the estimated CY 2014 combined impact on total allowed charges of the changes in the RVUs resulting from our proposed policy to adjust the RVUs to match the proposed revised MEI weights.
- *Column F (Cumulative Impact):* This column shows the estimated CY 2014 combined impact on total allowed charges of all the proposed changes in the previous columns.

TABLE 72—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY BY SELECTED PROPOSAL*

Specialty	Allowed charges (mil)	Impact of 2012 claims data, 90% utilization assumption, ultrasound changes, and other minor changes (percent)	Impact of OPD/ASC cap (percent)	Impact of MEI revision (percent)	Total (cumulative) impact (percent)
(A)	(B)	(C)	(D)	(E)	(F)
TOTAL	$86,995	0%	0%	0%	0%
01—ALLERGY/IMMUNOLOGY	213	−1	0	−2	−3
02—ANESTHESIOLOGY	1,862	0	0	3	3
03—CARDIAC SURGERY	355	0	0	2	2
04—CARDIOLOGY	6,425	2	0	0	2
05—COLON AND RECTAL SURGERY	158	0	0	0	0
06—CRITICAL CARE	273	0	0	2	2
07—DERMATOLOGY	3,113	0	0	−2	−2
08—EMERGENCY MEDICINE	2,929	0	0	3	3
09—ENDOCRINOLOGY	447	−1	1	0	0
10—FAMILY PRACTICE	6,358	0	1	0	1
11—GASTROENTEROLOGY	1,901	0	0	1	1
12—GENERAL PRACTICE	528	0	0	0	0
13—GENERAL SURGERY	2,236	0	0	1	1
14—GERIATRICS	231	0	1	1	2
15—HAND SURGERY	151	−1	1	0	0
16—HEMATOLOGY/ONCOLOGY	1,890	−1	1	−1	−1
17—INFECTIOUS DISEASE	635	0	0	2	2
18—INTERNAL MEDICINE	11,416	0	1	0	1
19—INTERVENTIONAL PAIN MGMT	640	−1	0	0	−1
20—INTERVENTIONAL RADIOLOGY	219	−1	−2	−1	−4
21—MULTISPECIALTY CLINIC/OTHER PHY	79	−1	0	1	0

TABLE 72—CY 2014 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY BY SELECTED PROPOSAL*—Continued

Specialty	Allowed charges (mil)	Impact of 2012 claims data, 90% utilization assumption, ultrasound changes, and other minor changes (percent)	Impact of OPD/ASC cap (percent)	Impact of MEI revision (percent)	Total (cumulative) impact (percent)
(A)	(B)	(C)	(D)	(E)	(F)
22—NEPHROLOGY	2,123	0	0	1	1
23—NEUROLOGY	1,498	0	−1	−1	−2
24—NEUROSURGERY	712	0	0	1	1
25—NUCLEAR MEDICINE	51	0	1	0	1
27—OBSTETRICS/GYNECOLOGY	688	0	0	0	0
28—OPHTHALMOLOGY	5,592	0	1	−1	0
29—ORTHOPEDIC SURGERY	3,683	−1	1	0	0
30—OTOLARNGOLOGY	1,128	−1	0	−1	−2
31—PATHOLOGY	1,134	1	−6	0	−5
32—PEDIATRICS	63	0	0	0	0
33—PHYSICAL MEDICINE	999	−1	1	0	0
34—PLASTIC SURGERY	367	0	1	−1	0
35—PSYCHIATRY	1,165	0	0	2	2
36—PULMONARY DISEASE	1,775	0	1	0	1
37—RADIATION ONCOLOGY	1,783	1	−4	−2	−5
38—RADIOLOGY	4,635	−1	0	0	−1
39—RHEUMATOLOGY	551	−3	1	−1	−3
40—THORACIC SURGERY	332	0	0	2	2
41—UROLOGY	1,858	−1	0	−1	−2
42—VASCULAR SURGERY	925	1	−3	0	−2
43—AUDIOLOGIST	56	0	1	0	1
44—CHIROPRACTOR	722	1	1	0	2
45—CLINICAL PSYCHOLOGIST	579	0	0	3	3
46—CLINICAL SOCIAL WORKER	408	0	0	3	3
47—DIAGNOSTIC TESTING FACILITY	779	−4	0	−3	−7
48—INDEPENDENT LABORATORY**	812	1	−25	−2	−26
49—NURSE ANES/ANES ASST	1,055	0	0	4	4
50—NURSE PRACTITIONER	1,937	0	1	0	1
51—OPTOMETRY	1,106	0	1	−1	0
52—ORAL/MAXILLOFACIAL SURGERY	44	0	−1	−1	−2
53—PHYSICAL/OCCUPATIONAL THERAPY	2,797	0	1	0	1
54—PHYSICIAN ASSISTANT	1,405	0	1	0	1
55—PODIATRY	1,975	−1	1	0	0
56—PORTABLE X-RAY SUPPLIER	110	1	1	−3	−1
57—RADIATION THERAPY CENTERS	62	0	−8	−5	−13
98—OTHER	25	0	1	0	1

*Table 72 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the January 2014 conversion factor change required under current law.

**PFS Payments only, which account for ~17% of Independent Laboratory payments.

2. CY 2014 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to two major factors. The first factor, as discussed in section II.A.4. of this proposed rule, is our proposal to cap the payments for certain nonfacility services at the facility rate plus the lower of the OPPS or ASC payment. The second factor, as discussed in section II.D., is our proposal to revise the Medicare Economic Index (MEI) and adjust the RVUs to match the new weights for work, PE, and MP.

In addition, a number of other changes contribute to the impacts shown in Table 71. These include a statutory change that requires us to use a 90 percent equipment utilization rate rather than the previously used 75 percent for expensive diagnostic imaging equipment as discussed in section II.A.2.f of this proposed rule, proposals to update direct practice expense inputs, as discussed in section II.A.5. of this proposed rule and proposals to adjust time for some services, as discussed in section II.B.3.c. of this proposed rule.

Table 72 shows the same information as provided in Table 71, but rather than isolating the policy impact on physician work, practice expense, and malpractice separately, Table 72 shows the impact of varied proposed policies on total RVUs.

b. Combined Impact

Column E of Table 71 and column F of Table 72 display the estimated CY 2014 combined impact on total allowed charges by specialty of all the proposed RVU changes. These impacts range from an increase of 3 percent for clinical social workers, clinical psychologists, nurse anesthetists, and emergency medicine, to a decrease of 26 percent for independent laboratories. Again, these impacts are estimated prior to the application of the negative CY 2014

conversion factor (CF) update applicable under the current statute.

Table 73 (Impact of Proposed Rule on CY 2014 Payment for Selected Procedures (Based on the March 2013 Preliminary Physician Update)) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included CY 2014 payment rates with and without the effect of the CY 2014 negative PFS CF update for comparison purposes. We selected these procedures from among the most commonly furnished by a broad spectrum of physician 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.

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TABLE 73: Impact of Proposed Rule on CY 2014 Payment for Selected Procedures (Based on the March 2013 Preliminary Physician Update)*

			Facility					Non-Facility				
CPT/ HCPCS [1]	MOD	Short Descriptor	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)
11721		Debride nail 6 or more	$24.50	$25.32	3%	$19.04	-22%	$44.91	$45.29	1%	$34.06	-24%
17000		Destruct premalg lesion	$57.16	$57.42	0%	$43.18	-24%	$83.36	$81.67	-2%	$61.42	-26%
27130		Total hip arthroplasty	$1,454.48	$1,481.54	2%	$1,114.10	-23%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,242.18	$1,262.91	2%	$949.69	-24%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,552.81	$1,582.11	2%	$1,189.73	-23%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,906.31	$1,944.12	2%	$1,461.95	-23%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,096.22	$1,112.04	1%	$836.24	-24%	NA	NA	NA	NA	NA
43239		Upper gi endoscopy biopsy	$174.54	$177.26	2%	$133.29	-24%	$359.28	$347.74	-3%	$261.49	-27%
66821		After cataract laser surgery	$325.26	$323.84	0%	$243.52	-25%	$344.99	$342.39	-1%	$257.47	-25%
66984		Cataract surg w/iol 1 stage	$667.87	$673.00	1%	$506.09	-24%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$520.55	$523.21	1%	$393.45	-24%	$538.92	$540.69	0%	$406.59	-25%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	$23.82	$23.90	0%	$17.97	-25%
71010	26	Chest x-ray 1 view frontal	$8.85	$9.27	5%	$6.97	-21%	$8.85	$9.27	5%	$6.97	-21%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$114.66	$114.49	0%	$86.09	-25%
77056	26	Mammogram both breasts	$42.19	$43.87	4%	$32.99	-22%	$42.19	$43.87	4%	$32.99	-22%

			Facility					Non-Facility				
CPT/ HCPCS[1]	MOD	Short Descriptor	CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)	CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.66	$81.32	0%	$61.15	-25%
77057	26	Mammogram screening	$34.02	$35.31	4%	$26.55	-22%	$34.02	$35.31	4%	$26.55	-22%
77427		Radiation tx management x5	$178.28	$185.46	4%	$139.46	-22%	$178.28	$185.46	4%	$139.46	-22%
88305	26	Tissue exam by pathologist	$36.74	$38.16	4%	$28.70	-22%	$36.74	$38.16	4%	$28.70	-22%
90935		Hemodialysis one evaluation	$71.11	$73.47	3%	$55.25	-22%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	$53.08	$54.92	3%	$41.30	-22%	$87.44	$86.67	-1%	$65.17	-25%
92014		Eye exam&tx estab pt 1/>vst	$80.29	$82.74	3%	$62.22	-23%	$126.23	$125.90	0%	$94.67	-25%
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$18.37	$18.19	-1%	$13.68	-26%
93010		Electrocardiogram report	$8.17	$8.56	5%	$6.44	-21%	$8.17	$8.56	5%	$6.44	-21%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$79.61	$77.75	-2%	$58.47	-27%
93307	26	Tte w/o doppler complete	$44.23	$46.01	4%	$34.60	-22%	$44.23	$46.01	4%	$34.60	-22%
93458	26	L hrt artery/ventricle angio	$315.73	$324.55	3%	$244.06	-23%	$315.73	$324.55	3%	$244.06	-23%
98941		Chiropract manj 3-4 regions	$30.62	$31.39	2%	$23.60	-23%	$36.40	$37.45	3%	$28.16	-23%
99203		Office/outpatient visit new	$75.19	$77.75	3%	$58.47	-22%	$108.19	$108.42	0%	$81.53	-25%
99213		Office/outpatient visit est	$49.67	$51.71	4%	$38.89	-22%	$72.81	$72.76	0%	$54.71	-25%
99214		Office/outpatient visit	$76.55	$79.18	3%	$59.54	-22%	$106.83	$107.35	0%	$80.73	-24%

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CPT/ HCPCS [1]	MOD	Short Descriptor	Facility					Non-Facility				
			CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)	CY 2013[2]	CY 2014[3] (pre update)	% Change (pre update)	CY 2014[4] (post update)	% Change (post update)
		est										
99222		Initial hospital care	$134.73	$138.38	3%	$104.06	-23%	NA	NA	NA	NA	NA
99223		Initial hospital care	$198.01	$203.65	3%	$153.14	-23%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.11	$39.23	3%	$29.50	-23%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$70.09	$72.40	3%	$54.44	-22%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$101.05	$104.14	3%	$78.31	-22%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$212.30	$218.63	3%	$164.41	-23%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$104.79	$107.35	2%	$80.73	-23%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$59.88	$61.70	3%	$46.40	-23%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$114.66	$118.05	3%	$88.77	-23%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.75	$223.26	3%	$167.89	-23%	$272.18	$273.91	1%	$205.98	-24%
99292		Critical care addl 30 min	$109.55	$112.70	3%	$84.75	-23%	$120.78	$123.05	2%	$92.53	-23%
99348		Home visit est patient	NA	NA	NA	NA	NA	$82.34	$84.53	3%	$63.56	-23%
99350		Home visit est patient	NA	NA	NA	NA	NA	$173.52	$177.61	2%	$133.56	-23%
G0008		Immunization admin	NA	NA	NA	NA	NA	$25.86	$24.97	-3%	$18.77	-27%

[1] CPT codes and descriptions are copyright 2012 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

[2] Payments based on the 2013 conversion factor of 34.0230.

[3] Payments based on the 2013 conversion factor of 34.0230, adjusted to 35.6653 to include the budget neutrality adjustment.

[4] Payments based on the estimated 2014 conversion factor of 25.7109 adjusted to 26.8199 to include a budget neutrality adjustment.

D. Effect of Proposed Changes to Medicare Telehealth Services Under the PFS

As discussed in section II.E.3 of this proposed rule, we are proposing to refine our definition of rural as it applies to HPSAs eligible for telehealth services as well as add transitional care management services to the list of Medicare telehealth services. While we expect these changes to increase access to care in rural areas, based on recent utilization of current Medicare telehealth services, including services similar to transitional care management, we estimate no significant impact on PFS expenditures from the proposed additions.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements we are proposing to update the GPCIs for each Medicare payment locality. The proposed GPCIs incorporate the use of updated data and cost share weights as discussed in II.E. The Act requires that updated GPCIs be phased in over two years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2014) and the fully implemented year (CY 2015). The GAFs reflect the use of the updated underlying GPCI data, and the proposed revised cost share weights. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual geographic adjustment to payment for any actual service will be different from the GAF to the extent that the proportions of work, PE and malpractice expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 22 payment localities where the fully implemented (CY 2015) GAF moves up by more than 1 percent (11 payment localities) or down by more than 2 percent (11 payment localities). The impacts on the proposed GPCIs are primarily attributed to the expiration of the 1.000 work GPCI floor. The use of updated underlying GPCI data and cost share weights has a minimal impact on locality GAFs. The total impact of the GPCI revisions is shown in the 2015 GPCI values of Addendum E.

We note that the proposed CY 2014 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in Addenda D and E reflect the elimination of the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act, which is set to expire prior to the implementation of the CY 2014 PFS.

F. Other Provisions of the Proposed Regulation

1. Rebasing and Revising Medicare Economic Index

The preliminary estimate of the proposed changes to the MEI for CY 2014 is a 0.1 percent decrease. This is based on an estimated 0.8 percent increase for CY 2014 under the current MEI compared to a 0.7 percent increase for CY 2014 under the proposed revised MEI.''

2. Coverage of Items and Services Furnished in FDA-Approved Investigational Device Exemption (IDE) Clinical Trials

We are proposing a transparent centralized review process that would be more efficient by reducing the burden for stakeholders. Once the IDE coverage process is centralized, there will be a single entity making the IDE coverage decision. This also eliminates duplicative reviews by Medicare local contractors and the numerous applications sent to contractors by stakeholders requesting IDE coverage. We believe that a centralized review process will not significantly reduce the number of IDE devices currently covered. Therefore, this rule will not result in an extra burden to the public.

3. Ultrasound Screening for Abdominal Aortic Aneurysms

As discussed in section III.B. of this proposed rule, section 1861(s)(2)(AA) of the Act, with implementing regulations at § 410.19, authorizes Medicare coverage of ultrasound screening for abdominal aortic aneurysms (''AAA screening''). We are proposing to modify § 410.19 to allow coverage of one-time AAA screening without receiving a referral as part of the IPPE, for beneficiaries that meet certain other eligibility criteria (a family history of AAA or, for men aged 65–75, a history of smoking). Approximately 45 percent of men aged 65–75 have a history of smoking. It is unknown how many individuals have a family history of AAA or how many beneficiaries will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

4. Modification to Medicare Coverage of Colorectal Cancer Screening

As discussed in section III.C. of this proposed rule, sections 1861(s)(2)(R) and 1861(pp)(1) of the Act, and implementing regulations at 42 CFR 410.37 authorize Medicare coverage of screening FOBT. We are proposing to modify § 410.37(b) to allow attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists to furnish orders for screening FOBTs. While there may be an increase in utilization, particularly in rural areas, it is unknown how many individuals will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

5. Ambulance Fee Schedule

As discussed in section III.D. of this proposed rule, section 604(a) through (c) of the ATRA require the extension of certain add-on payments for ground ambulance services and the extension of certain rural area designations for purposes of air ambulance payment. In addition, as discussed in section III.D. of this proposed rule, section 637 of the ATRA (which added section 1834(l)(15) of the Act) specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The ambulance extender provisions and the mandated 10 percent rate decrease discussed above are enacted through legislation that is self-implementing. We are proposing to amend the regulation text at § 414.610 only to conform the regulations to these self-implementing statutory requirements. As a result, we are not making any policy proposals associated with these legislative provisions and there is no associated regulatory impact.

6. Clinical Laboratory Fee Schedule

We are proposing to add language to the Code of Federal Regulations to codify authority provided by statute and to establish a process under which we will systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount. We are also proposing a definition for the term technological changes. Adjustments made under the new process could both increase fee schedule amounts and provide for reductions in existing amounts. We cannot estimate a net impact at this time.

7. Liability for Overpayments to or on Behalf of Individuals Including Payments to Providers or Other Persons

As discussed in section III.M. of this proposed rule, we are proposing to change the timing of the triggering event for the ''without fault'' and ''against equity and good conscience'' presumptions. As a result, there would be an estimated savings of $0.5 billion over 10 years.

8. Physician Compare Web Site

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

9. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are making additional proposals for 2014, this section modifies the impact statement provided for 2014 in the CY 2013 PFS final rule with comment period. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter ''the PQRS Reporting Experience''). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/*. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27 percent of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 is accurate.

With respect to the estimate amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (that is, a bonus payment equal to 0.5 percent of the total allowed Part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting, a reduction of 1.0 percent from 2011. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27 percent of 1 million eligible professionals) 270,000 eligible professionals. At $1,059 per eligible professional, the PQRS would distribute approximately $286 million in incentive payments in 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- The proposals for reporting for the PQRS for the 2014 incentive and 2016 payment adjustment would be established as proposed in this CY 2014 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would attempt to report PQRS quality measures data with the intention of earning the 2014 PQRS incentive. Therefore, an eligible professionals or group practice would report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

For an eligible professional who wishes to participate in the PQRS as an individual, the eligible professional need not indicate his/her intent to participate. The eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in the PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in the PQRS would be approximately $80 ($16/hour × 5 hours).

With respect to an eligible professional who participates in the PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims will range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. Using an average labor cost of $40/hour, we estimate that time cost of reporting for an eligible professional via claims would range from $1.50 (2.25 minutes or 0.0375 hours × $40/hour) to $72.00 (108 minutes or 1.8 hours × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we proposed that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional would report would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we are proposing to reduce the reporting threshold to 50 percent, we estimate that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimate that the

total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($1.50/per reported case × 6 reported cases) $9.00 to ($72.00/reported case × 6 reported cases) $432.

With respect to an eligible professional or group practice who participates in the PQRS via a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry, we believe there would be little to no burden associated for an eligible professional or group practice to report PQRS quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. While we note that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, EHR data submission vendor, or qualified clinical data registry, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, EHR data submission vendor product, or qualified clinical data registry in our burden estimates.

Unlike eligible professionals who choose to report individually, we note that eligible professionals choosing to participate as part of a group practice under the GPRO must indicate their intent to participate in the PQRS as a group practice. The total burden for group practices who submit PQRS quality measures data via the proposed GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for the PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in the PQRS as a GPRO, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in the PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96. With respect to reporting, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS quality measures data for the proposed reporting options in an applicable year would be ($40/hour × 79 hours) $3,160.

Aside from the burden of eligible professionals and group practices participating in the PQRS, we believe that vendors of registries, qualified clinical data registries, direct EHR products, and EHR data submission vendor products incur costs associated with participating in the PQRS. Please note that we have proposed requirements for a new reporting mechanism in this CY 2014 PFS proposed rule—the qualified clinical data registry. For purpose of these burden estimates, we believe that, at least in its initial stage, vendors of a qualified clinical data registry would have burden estimates similar to traditional registries, as we believe many of the vendors seeking to become qualified as a clinical data registry in the PQRS will be existing qualified registries.

With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years for PQRS, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process for both traditional registries and clinical data registries, we estimate that it will take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimate that it would cost a traditional registry and clinical data registry ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, we believe the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in the PQRS. Therefore, we believe there would be little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for the PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years under the PQRS, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that we are not proposing to continue to require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data.

In addition to the GPRO web interface, please note that we have proposed a new reporting mechanism that would be available to group practices comprised of 25+ eligible professionals: the certified survey vendor. With respect to using a certified survey vendor, we believe there would be little to no burden associated for a group practice to report the CG CAHPS survey data to CMS, because the selected reporting mechanism submitted the quality measures data for the group practice. While there may be start-up costs associated with purchasing a certified survey vendor, we believe that a group practice would not purchase a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of purchasing a certified survey vendor in our burden estimates.

TABLE 74—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA PER ELIGIBLE PROFESSIONAL

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80
Individual EP: Claims	1.8	6	9	40	3,888
Individual EP: Registry	N/A	1	N/A	N/A	Minimal
Individual EP: EHR	N/A	1	N/A	N/A	Minimal
Group Practice: Self-Nomination	6.0	1	N/A	16	96
Group Practice: Reporting	79	1	N/A	40	3,160

TABLE 75—ESTIMATED COSTS PER VENDOR TO PARTICIPATE IN THE PQRS

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$16	$160

10. Medicare EHR Incentive Program

Please note that the requirements for meeting the clinical quality measures (CQM) component of achieving meaningful use for the EHR Incentive Program in 2014 were established in a standalone final rule published on September 4, 2012 (77 FR 53968). The proposals contained in this CY 2014 PFS proposed rule merely propose alternative methods to report CQMs to meet the CQM component of achieving meaningful use for the EHR Incentive Program in 2014. We believe any impacts these proposals would have are absorbed in the impacts discussion published in the EHR Incentive Program final rule published on September 4, 2012.

11. Medicare Shared Savings Program

Please note that the requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule for the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67962). The proposals for the Medicare Shared Savings Program set forth in the CY 2014 MPFS proposed rule expand the incorporation of reporting requirements and incentive payments related to PQRS under section 1848 to include reporting requirements related to the payment adjustment. Since ACO participants and ACO provider/suppliers will not have to report PQRS separately to avoid the payment adjustment, this reduces the quality reporting burden for ACO participants participating in the Shared Savings Program. There is no impact for the additional proposals related to requirements for setting benchmarks or for scoring the CAHPS measure modules.

12. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The changes to the Physician Feedback Program in section III.K. of this proposed rule would not impact CY 2014 physician payments under the Physician Fee Schedule. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the Physician Quality Reporting System to determine and understand how the value modifier could affect their payments.

13. Existing Standards for E-Prescribing Under Medicare Part D and Identification

This section of the proposed rule imposes no new requirements because use of the official Part D e-prescreening standards; NCPDP SCRIPT 10.6, Formulary and Benefit 3.0 are voluntary, and as such, it will not have a significant economic impact on a substantial number of small entities, small rural hospitals or state, local, or tribal governments or on the private sector.

14. Chiropractic Services Demonstration

As discussed in section III.M. of this proposed rule, we are continuing the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the BN requirement in section 651(f)(1)(B) of the MMA. We initiated this recoupment in CY 2010 and this will be the fifth and final year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup $10 million each year through adjustments to payments under the PFS for chiropractic CPT codes in CYs 2010 through 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. While OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: $540 million in 2010; $520 million in 2011; and $580 million in 2012. In total, CMS recouped $32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately $580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately $11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately $44.4 million of the $50 million required for budget neutrality.

CMS plans to recoup the remaining funds, approximately $5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage, which by our preliminary estimates is one percent if the approximately 25 percent reduction in physician payments takes effect in 2014. If the statute is amended to avoid the physician payment reduction, we will reduce the recoupment percentage as appropriate to ensure the recoupment does not exceed $50 million. For instance, if the statute is amended to provide for a zero percent PFS update, we would reduce the recoupment percentage to approximately 0.7 percent.

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 value-based payment modifier to adjust physician payment beginning in CY 2015; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS and the capping certain nonfacility services at the facility rate plus the lower of the OPPS or ASC rate; 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 73, the CY 2013 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $108.05, which means that in CY 2013 a beneficiary would be responsible for 20 percent of this amount, or $21.61. Based on this proposed rule, using the current (CY 2013) CF of 34.0376, adjusted to 35.6652 to include budget neutrality, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 73, is $113.15, which means that, in CY 2014, the proposed beneficiary coinsurance for this service would be $22.63.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 76 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this proposed rule. This estimate includes the CY 2014 incurred benefit impact associated with the estimated CY 2014 PFS conversion factor update based on the FY 2014 President's Budget baseline.

TABLE 76—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of $19.6 billion for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2014 Annualized Monetized Transfers	Estimated increase in payment of $286 million.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of $50 million for liability for overpayments to or on behalf of individuals including payments to providers or other persons.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 77—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2014 Annualized Monetized Transfers of beneficiary cost coinsurance.	$29 million.
From Whom to Whom?	Beneficiaries to Federal Government.
Category	**Cost**
CY 2014 Annualized Monetized Cost to eligible professionals of Participating in the PQRS Program.	$66.6 million.

J. Conclusion

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

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

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

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

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

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 propose to amend 42 CFR chapters IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1862(m), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395y(m), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.201 is amended by adding paragraph (a)(3) and revising paragraph (b) to read as follows:

§ 405.201 Scope of subpart and definitions.

(a) * * *

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

ClinicalTrials.gov refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare items and services.

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Pivotal studies or trials refer to clinical investigations designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects. It may or may not be preceded by an early and/or a traditional feasibility study.

Routine care items and services refer to items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are furnished in either the experimental or the control arms of a clinical trial and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical trial.

Superiority studies or trials refers to studies or trials that are intended to demonstrate at some prespecified level of confidence that the effect of an investigational treatment is superior to that of an active control by more than a prespecified margin.

■ 3. Section 405.207 is amended by revising paragraph (b)(2) to read as follows:

§ 405.207 Services related to a non-covered device.

* * * * *

(b) * * *

(2) Routine care items and services related to experimental/investigational (Category A) devices as defined in § 405.201(b); and furnished in conjunction with an FDA-approved clinical trial that meet the IDE study standards in § 405.212.

* * * * *

■ 4. Section 405.211 is revised to read as follows:

§ 405.211 Coverage of items and services in FDA approved IDE studies.

(a) *Requirements.* CMS review includes the following items and supporting materials as needed:

(1) The FDA approval letter.

(2) IDE study protocol.

(3) IRB approval letter.

(4) ClinicalTrial.gov identifier.

(b) *Coverage of routine care items and services for Category A devices.* Medicare may cover routine care items and services furnished in any FDA-approved Category A IDE study if the criteria in § 405.212(a)(1) through (13) are met. Medicare covers routine care items and services furnished in any FDA-approved Category A IDE study if the criteria in § 405.212(a) and (b) are met.

(c) *Coverage of Category B IDE devices and routine care.* Medicare may cover a Category B IDE device and routine care items and services furnished in any FDA-approved Category B IDE study if the criteria in § 405.212(a)(1) through (13) are met. Medicare covers a Category B IDE device and routine care items and services furnished in any FDA-approved Category B IDE study if the criteria in § 405.212(a) and (c) are met.

(d) *Coverage of Category A routine services and Category B IDE devices and routine care that do not wholly fall under § 405.212 (b) or (c).* If an IDE device is furnished in an FDA-approved IDE study that does not wholly fall under § 405.212(b) or (c), CMS considers whether the study's attainment of the criteria in § 405.212 (a) are sufficient to mitigate the failure to meet § 405.212(b) or (c).

(e) *Notification.* All CMS-approved IDE studies will be posted on the CMS coverage Web site and published in the **Federal Register**.

■ 5. Section 405.212 is added to read as follows:

§ 405.212 IDE study criteria.

(a) All category A and B IDE studies must conform to the following criteria for Medicare coverage under § 405.211:

(1) The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.

(2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

(3) The study results are not anticipated to unjustifiably duplicate existing knowledge.

(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to answer the research question(s) being asked in the study.

(5) The study is sponsored by an organization or individual capable of completing it successfully.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR part 46.

(7) All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.

(8) The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.

(9) Where appropriate, the clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.

(10) The study is registered on the ClinicalTrials.gov Web site and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject.

(11) The study protocol specifies the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. The release should be hastened if the study is terminated early. The results must be made public within 24 months

of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

(12) The study protocol explicitly discusses subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the study. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

(13) The study protocol explicitly discusses how the results are or are not expected to be generalizable to subsections of the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

(b) Medicare covers routine care items and services in an FDA-approved Category A IDE study that meets the requirements in paragraph (a) of this section and the study is the following:

(1) A pivotal study.

(2) A superiority study design.

(c) Medicare covers the IDE device and routine care items and services in an FDA-approved Category B IDE study that meets the requirements in paragraph (a) of this section and the study is the following:

(1) A pivotal study.

(2) A superiority study design.

■ 6. Section 405.350 is amended by revising paragraph (c) to read as follows:

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

* * * * *

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in which notice was sent to such individual that such amount had been paid.

■ 7. Section 405.355 is amended by revising paragraph (b) to read as follows:

§ 405.355 Waiver of adjustment or recovery.

* * * * *

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.

■ 8. Section 405.2413 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

The revision and addition reads as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a physician; and

* * * * *

■ 9. Section 405.2415 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

■ D. Revising paragraph (b).

The revision and addition reads as follows:

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

* * * * *

(b) The direct supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

* * * * *

■ 10. Section 405.2452 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

■ D. Revising paragraph (b).

The revision and addition reads as follows:

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker or physician; and

* * * * *

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the Federally qualified health center.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 11. 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).

§ 410.19 [Amended]

■ 12. In § 410.19(a) amend the definition of ''eligible beneficiary'' by removing paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.

■ 13. Section 410.26 is amended by—

■ A. Revising paragraph (a)(1).

■ B. Redesignating paragraph (b)(7) and (8) as paragraph (b)(8) and (9), respectively.

■ C. Adding new paragraph (b)(7).

The revision and addition reads as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(1)*Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the

individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(7) Services and supplies must be furnished in accordance with applicable State law.

* * * * *

■ 14. Section 410.37 is amended by revising paragraph (b) to read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(b) *Condition for coverage of screening fecal-occult blood tests.* Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

■ 15. Section 410.59 is amended by—

■ A. Adding paragraph (e)(1)(iv).

■ B. Revising paragraph (e)(2)(iv).

■ C. Adding paragraph (e)(2)(v).

The revision and additions reads as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(e) * * *

(1) * * *

(iv) Outpatient occupational therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(2)* * *

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements.

* * * * *

■ 16. Section 410.60 is amended by—

■ A. Adding paragraph (e)(1)(iv).

■ B. Revising paragraph (e)(2)(v).

■ C. Adding paragraph (e)(2)(vi).

■ D. In paragraph (e)(3), removing the phrase ''or CAH'' .

The additions and revision read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(e) * * *

(1) * * *

(iv) Outpatient physical therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(2) * * *

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements.

* * * * *

■ 17. Section 410.71 is amended by revising paragraph (a)(2) to read as follows:

§ 410.71 Clinical psychologist services and services and supplies incident to clinical psychologist services.

(a) * * *

(2) Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of § 410.26 are met.

* * * * *

■ 18. Section 410.74 is amended by revising paragraph (b) to read as follows:

§ 410.74 Physician assistants' services.

* * * * *

(b) *Services and supplies furnished incident to a physician assistant's services.* Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of § 410.26 are met.

* * * * *

■ 19. Section 410.75 is amended by revising paragraph (d) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.

* * * * *

■ 20. Section 410.76 is amended by revising paragraph (d) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(d) *Services and supplies furnished incident to clinical nurse specialists' services.* Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of § 410.26 are met.

* * * * *

■ 21. Section 410.77 is amended by revising paragraph (c) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(c) *Incident to services: Basic rule.* Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.

* * * * *

■ 22. Section 410.78 is amending by revising paragraph (b) introductory text and paragraph (b)(4) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every three days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) of this chapter and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services

furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

(4) Originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000 regardless of its geographic location.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 23. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 24. Section 411.15 is amended by revising paragraph (o)(2) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(o) * * *

(2) Furnished in accordance with the CMS criteria established in § 405.211(b).

* * * * *

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

■ 25. 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)).

■ 26. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) *Emergency department or initial inpatient telehealth consultations.* The Medicare payment amount for emergency department or initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) *Follow-up inpatient telehealth consultations.* The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

* * * * *

■ 27. Section 414.90 is amended by—

■ A. Amending paragraph (b) to—

■ 1. Revise the definition of ''Administrative claims''.

■ 2. Add the definition of ''Certified survey vendor''.

■ 3. Revise the definition of ''Measures group''.

■ 4. Add the definition of ''Qualified clinical data registry''.

■ B. Adding paragraphs (c)(5), (e)(2), and (f)(4).

■ C. Revising the paragraph headings to paragraphs (f) introductory text, (g) introductory text, and (h) introductory text.

■ D. Revising paragraphs (g)(3) introductory text.

■ E. Redesignating paragraph (g)(3)(v) as (g)(3)(vi).

■ F. Adding new paragraph (g)(3)(v).

■ G. Revising paragraph (h)(3) introductory text.

■ H. Adding paragraph (h)(3)(vi).

■ I. Revising paragraph (j).

The revisions and additions read as follows:

§ 414.90 Physician Quality Reporting System.

* * * * *

(b) * * *

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on PQRS quality measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

Certified survey vendor means a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

* * * * *

Measures group means a subset of six 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.

* * * * *

Qualified clinical data registry means a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must do the following functions:

(i) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and

specifications, risk models, and measures.

(ii) Provide timely feedback, at least quarterly on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory participation in the clinical quality data registry.

(iii) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

* * * * *

(c) * * *

(5) The Secretary shall treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (g) of this section), if the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as defined in paragraph (b) of this section).

(i) For purposes of this paragraph, the reporting period for the 2014 PQRS incentive is the 12-month period from January 1 through December 31 of such program year.

(ii) [Reserved].

* * * * *

(e) * * *

(2) The Secretary shall treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (h) of this section), if the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as defined in paragraph (b) of this section).

(i) For purposes of this paragraph, the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(ii) [Reserved].

(f) *Use of consensus-based quality measures for satisfactory reporting.* * * *

* * * * *

(4) These criteria do not apply to measures reported by qualified clinical data registries for purposes of satisfactory participation.

* * * * *

(g) *Satisfactory reporting requirements for the incentive payments.* * * *

* * * * *

(3) *Reporting mechanisms for group practices.* With the exception of a group practice (as defined in paragraph (b) of this section) who wishes to participate in the Physician Quality Reporting System using the certified survey vendor mechanism (as specified in paragraph (g)(3)(v) of this section), a group practice must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

* * * * *

(v) *Certified survey vendors.* For 2014 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional reporting mechanism in order to meet the criteria for satisfactory reporting for the incentive payments.

(h) Satisfactory reporting for the payment adjustments. * * *

* * * * *

(3) *Reporting mechanisms for group practices.* With the exception of a group practice (as defined in paragraph (b) of this section) who wishes to participate in the Physician Quality Reporting System using the certified survey vendor mechanism (as specified in paragraph (g)(3)(v) of this section), a group practice participating in the Physician Quality Reporting System must report information on Physician Quality Reporting System quality measures identified by CMS in one of the following manners:

* * * * *

(vi) Certified Survey Vendors. For 2014 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional reporting mechanism in order to meet the criteria for satisfactory reporting for the payment adjustment.

* * * * *

(j) *Informal review.* Eligible professionals (or in the case of group practices defined in paragraph (b) of this section) may seek an informal review of the determination that an eligible professional (or in the case of group practices defined in paragraph (b) of this section) did not satisfactorily submit data on quality measures under the Physician Quality Reporting System or an eligible professional did not satisfactorily participate in a qualified clinical data registry under the Physician Quality Reporting System.

* * * * *

■ 28. Section 414.511 is added to subpart G to read as follows:

§ 414.511 Adjustments to the Clinical Laboratory Fee Schedule based on Technological Changes.

(a) CMS may make adjustments to the as CMS determines are justified by technological changes.

(b) Technological changes are changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.

(c) CMS will propose and finalize any adjustments to the fee schedules as CMS determines are justified by technological changes in the **Federal Register**.

■ 29. Section 414.610 is amended by—

■ A. Revising paragraphs (c)(1)(ii) and (c)(5)(ii).

■ B. Adding paragraph (c)(8).

■ C. Revising paragraph (h).

The revisions and addition read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2013, ambulance services originating in:

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2013, 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.

* * * * *

(8) For ambulance services furnished on or after October 1, 2013 consisting of non-emergency basic life support (BLS)

services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through June 30, 2013.

■ 30. Section 414.1210 is amended by revising paragraphs (a) and (c) to read as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable:

(1) For the CY 2015 payment adjustment period, to physicians in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) For the CY 2016 payment adjustment period, to physicians in groups with 10 or more eligible professionals based on the performance period described at § 414.1215(b).

* * * * *

(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 of physicians subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the PQRS group registration process during the applicable performance period described at § 414.1215. Groups of physicians are removed from the PECOS-generated list if, based on a claims analysis, the group of physicians 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.

■ 31. Section 414.1215 is amended by adding paragraph (c) to read as follows:

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

* * * * *

(c) The performance period is calendar year 2015 for value-based payment modifier adjustments made in the calendar year 2017 payment adjustment period.

■ 32. Section 414.1220 is revised to read as follows:

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Groups of physicians subject to the value-based payment modifier (or individual eligible professionals within such groups) may submit data on quality measures as specified under the Physician Quality Reporting System using the reporting mechanisms for which they are eligible.

■ 33. 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 groups of physicians or individual eligible professionals 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 group of physicians or individual eligible professionals within such group submits data on such measures.

■ 34. Section 414.1235 is revised to read as follows:

§ 414.1235 Cost measures.

(a) *Included measures.* Beginning with the CY 2016 payment adjustment period, costs for groups of physicians subject to the value-based payment modifier are assessed based on a cost composite comprised of the following 6 cost measures (only the measures identified in paragraphs (a)(1) through (5) of this section are included for the value-based payment modifier for the CY 2015 payment adjustment period):

(1) Total per capita costs for all attributed beneficiaries.

(2) Total per capita costs for all attributed beneficiaries with diabetes.

(3) Total per capita costs for all attributed beneficiaries with coronary artery disease.

(4) Total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease.

(5) Total per capita costs for all attributed beneficiaries with heart failure.

(6) Medicare Spending per Beneficiary associated with an acute inpatient hospitalization.

(b) *Included payments.* Cost measures enumerated in paragraph (a) of this section include all fee-for-service payments made under Medicare Part A and Part B.

(c) *Cost measure adjustments.* (1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for the measures listed at paragraphs (a)(1) through (5) of this section.

(3) The beneficiary's age and severity of illness are used to adjust the Medicare Spending per Beneficiary measure as specified in paragraph (a)(6) of this section.

■ 35. 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 of physicians 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, a MSPB episode is attributed to a group of physicians subject to the value-based payment modifier if any eligible professional in the group submits a Medicare Part B claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.

■ 36. Section 414.1255 is revised to read as follows:

§ 414.1255 Benchmarks for cost measures.

(a) For the CY 2015 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians that are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

(b) Beginning with the CY 2016 payment adjustment period, the cost

measures of a group of physicians subject to the value-based payment modifier are adjusted to account for the group'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 of physicians that include that specialty.

■ 37. Section 414.1260 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 414.1260 Composite scores.

* * * * *

(b) * * *

(1) * * *

(i) Total per capita costs for all attributed beneficiaries: Total per capita costs measure and Medicare Spending per Beneficiary measure; and

* * * * *

■ 38. Section 414.1270 is revised to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

(a) For the CY 2015 payment adjustment period:

(1) *Downward payment adjustments.* A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if—

(i) Such group neither self-nominates for the PQRS GPRO and reports at least one measure, nor elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(A) Such adjustment will be −1.0 percent.

(B) [Reserved].

(ii) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs; low quality and average costs; or average quality and high costs).

(A) Such adjustment will not exceed −1.0 percent as specified in § 414.1275(c)(1).

(B) [Reserved].

(2) *No payment adjustments.* There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either:

(i) Self-nominates for the PQRS GPRO and reports at least one measure; or

(ii) Elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(3) *Upward payment adjustments.* If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a)(1) of this section and applied as specified in § 414.1275(c)(1).

(b) For the CY 2016 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group of physicians 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 2016 as specified by CMS; and

(ii) Seventy percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS.

(2) For a group of physicians comprised of 100 or more eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(2).

(3) For a group of physicians comprised of between 10 and 99 eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(2), except that such adjustment will be 0.0 percent if the group of physicians is 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 of physicians 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 under that reporting mechanism, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

(5) 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 in its cost composite with at least 20 cases.

■ 39. Section 414.1275 is amended by revising paragraphs (a) and (c) and (d) introductory text to read as follows:

The revisions 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 of physicians 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)(1) The following value-based payment modifier percentages apply to the CY 2015 payment adjustment period:

CY 2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+2.0x*	+1.0x*	+0.0
Average quality	+1.0x*	+0.0%	−0.5
Low quality	+0.0%	−0.5	−1.0

*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.

(2) The following value-based payment modifier percentages apply to the CY 2016 payment adjustment period:

CY 2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+2.0x*	+1.0x*	+0.0
Average quality	+1.0x*	+0.0%	−1.0
Low quality	+0.0%	−1.0%	−2.0

*Groups of physicians 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) Groups of physicians 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 2015 payment adjustment period elect the quality-tiering approach or for the CY 2016 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 40. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 41. Section 423.160 is amended by—

■ A. Revising paragraphs (b)(1)(i) through (iii).

■ B. Adding paragraphs (b)(1)(iv), (b)(5)(i) through (iii), and (c)(1)(vi).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(i) Prior to April 1, 2009, the standards specified in paragraphs (b)(2)(i), (b)(3)–(b)(4), (b)(5)(i), and (b)(6).

(ii) On or after April 1, 2009, to [59 days after publication of the final rule], 2013, the standards specified in paragraphs (b)(2)(ii), (b)(3) through (b)(4), (b)(5)(i) and (b)(6).

(iii) From [60 days after publication of the final rule] until June 30, 2014 the standards specified in paragraphs (b)(2)(ii), (b)(3) and (4), (b)(5)(ii), and (b)(6).

(iv) From July 1, 2014, the standards specified in paragraphs (b)(2)(ii), (b)(3) through (b)(4), (b)(5)(iii) and (b)(6).

* * * * *

(5) * * *

(i) *Formulary and benefits.* Before The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(ii) *Formulary and benefits.* On The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section), or The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), January 2011(incorporated by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(iii) Formulary and benefits. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), January 2011 (incorporated by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

* * * * *

(c) * * *

(1) * * *

(vi) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published January 2011.

* * * * *

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 425.308 is amended by revising paragraph (e) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(e) *Results of claims based measures.* Quality measures reported using a CMS web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

■ 44. Section 425.502 is amended by revising paragraph (b)(2) to read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(b) * * *

(2)(i) CMS will define the quality benchmarks using Medicare Advantage and fee-for-service Medicare data. When data are unavailable, inadequate, or unreliable to set the quality benchmarks, CMS will set the benchmarks using flat percentages.

(ii) CMS will reduce performance rate clustering in tightly clustered quality measures.

(A) A tightly clustered measure is defined as a measure where there is less than a 6.0 percentage point spread between the 30th and 90th deciles.

(B) For tightly clustered measures, CMS will apply a 1.0 fixed percentage point spread between each deciles, using the 60th percentile as the starting point.

(C) CMS does not apply the methodology in this paragraph (b)(2)(ii) to measures scored as ratios.

* * * * *

■ 45. Section 425.504 is amended by:

■ A. Revising the section heading.

■ B. Revising paragraphs (a)(1), (b) heading, and (b)(1).

■ C. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

(a) * * *

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using a CMS web interface, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System

incentive under the Shared Savings Program.

* * * * *

(b) *Physician Quality Reporting System payment adjustment for 2015.* (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit one of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

* * * * *

(c) Physician Quality Reporting System payment adjustment for 2016 and subsequent years.

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit one of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(ii) ACOs, on behalf of its ACO provider/suppliers who are eligible professionals, must satisfactorily report all of the ACO GPRO measures determined under § 425.500 using a CMS web interface for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2016 and subsequent years, each ACO supplier/provider who is an eligible professional, will receive a payment adjustment, as described in § 414.90(e).

(4) ACO participant TINs and individual ACO providers/suppliers billing through an ACO participant TIN who are eligible professionals cannot satisfactorily report for purposes of a Physician Quality Reporting System payment adjustment outside of the Medicare Shared Savings Program for 2016 and subsequent years.

(5) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2016 and subsequent years, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e).

(d) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 26, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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