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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 410, 414, 415, 421, 423, 425, 486, and 495**

**[CMS-1590-P]**

**RIN 0938-AR11**

# Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013

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

**ACTION:** Proposed rule.

**SUMMARY:** This major proposed rule addresses changes to the physician fee schedule, payments for Part B drugs, 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. It would also implement provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it would implement statutory changes regarding the termination of non-random prepayment review under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Finally, this proposed rule also includes a discussion regarding the Chiropractic Services Demonstration program.

**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 [OFR—insert date 60 days after the date of filing for public inspection at OFR.]

**ADDRESSES:** In commenting, please refer to file code CMS-1590-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-1590-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1590-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:**

Corinne Axelrod, (410) 786-5620, for any physician payment issue not identified below.

Ryan Howe, (410) 786-3355, for issues related to practice expense methodology and direct practice expense inputs, telehealth services, and issues related to primary care and care coordination.

Sara Vitolo, (410) 786-5714, for issues related to potentially misvalued services, malpractice RVUs, molecular pathology, and payment for new preventive service HCPCS G-codes.

Ken Marsalek, (410) 786-4502, for issues related to the multiple procedure payment reduction and payment for the technical component of pathology services.

Michael Moore, (410) 786-6830, for issues related to geographic practice cost indices and the sustainable growth rate.

Pam West, (410) 786-2302, for issues related to therapy services.

Chava Sheffield, (410) 786-2298, for issues related to certified registered nurse anesthetists.

Roberta Epps, (410)786-4503, for issues related to portable x-ray.

Anne Tayloe-Hauswald, (410) 786-4546, for issues related to ambulance fee schedule and Part B drug payment.

Amanda Burd, (410) 786-2074, for issues related to the DME provisions.

Debbie Skinner, (410) 786-7480, for issues related to non-random prepayment complex medical review.

Latesha Walker, (410) 786-1101, for issues related to ambulance coverage-physician certification statement.

Alexandra Mugge, (410) 786-4457, for issues related to physician compare.

Christine Estella, (410) 786-0485, for issues related to the physician quality reporting system, incentives for e-prescribing, and Medicare shared savings program.

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

Gift Tee, (410) 786-9316, for issues related to the Physician Feedback Reporting Program and Value-Based Payment Modifier.

Jamie Hermansen, (410) 786-2064, for issues related to Medicare coverage for hepatitis B vaccine.

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

**SUPPLEMENTARY INFORMATION:**

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

**Table of Contents**

I. Executive Summary and Background

II. Provisions of the Proposed Rule

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

B. Potentially Misvalued Codes Under the Physician Fee Schedule

C. Malpractice RVUs

D. Geographic Practice Cost Indices (GPCIs)

E. Medicare Telehealth Services for the Physician Fee Schedule

F. Extension of Payment for Technical Component of Certain Physician Pathology Services

G. Therapy Services

H. Primary Care and Care Coordination

I. Payment for Molecular Pathology Services

J. Payment for New Preventive Services HCPCS G Codes

K. Certified Registered Nurse Anesthetists and Chronic Pain Management Services

L. Ordering of Portable X-Ray Services

III. Other Provisions of the Proposed Regulation

A. Ambulance Fee Schedule

B. Part B Drug Payment: Average Sales Price (ASP) Issues

C. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

D. Elimination of the Requirement for Termination of Non-random Prepayment Complex Medical Review

E. Ambulance Coverage-Physician Certification Statement

F. Physician Compare Website

G. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

H. Electronic Prescribing (eRx) Incentive Program

I. Medicare Shared Savings Program

J. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

K. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

L. Medicare Coverage of Hepatitis B Vaccine

M. Updating Existing Standards for E-prescribing under Medicare Part D and Lifting the LTC Exemption

IV. Technical Corrections

A. Waiver of Deductible for Surgical Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test and Colorectal Cancer Screening Test Definition

V. Collection of Information Requirements

VI. Response to Comments

VII. Regulatory Impact Analysis

**Acronyms**

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:

| | |
|---|---|
| AHRQ | [HHS] Agency for Healthcare Research and Quality |
| AMA | American Medical Association |
| AMA RUC | AMA [Specialty Society] Relative [Value] Update Committee |
| ARRA | American Recovery and Reinvestment Act (Pub. L. 111-5) |
| 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) |
| BIPA | [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106-554) |
| BLS | Bureau of Labor Statistics |
| BN | Budget neutrality |
| CAH | Critical access hospital |
| CBSA | Core-Based Statistical Area |

| | |
|---|---|
| CF | Conversion factor |
| CFC | Conditions for Coverage |
| CFR | Code of Federal Regulations |
| CNS | Clinical nurse specialist |
| CoPs | Conditions of Participation |
| CORF | Comprehensive Outpatient Rehabilitation Facility |
| CPI | Consumer Price Index |
| CPT | [Physicians] Current Procedural Terminology (CPT codes, descriptions and other data only are copyright 2011 American Medical Association. All rights reserved.) |
| CRNA | Certified registered nurse anesthetist |
| CY | Calendar year |
| DHS | Designated health services |
| DME | Durable medical equipment |
| DMEPOS | Durable medical equipment, prosthetics, orthotics, and supplies |
| DOTPA | Development of Outpatient Therapy Payment Alternatives |
| DRA | Deficit Reduction Act of 2005 (Pub. L. 109-171) |
| E/M | Evaluation and management |
| EHR | Electronic health record |
| EMTALA | Emergency Medical Treatment and Active Labor Act (part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272) |
| eRx | Electronic prescribing |
| FFS | Fee-for-service |
| FR | **Federal Register** |
| GAF | Geographic adjustment factor |
| GAO | [U.S.] Government Accountability Office |

| | |
|---|---|
| GPRO | Group Practice Reporting Option |
| GPCI | Geographic practice cost index |
| HAC | Hospital-acquired conditions |
| HCPCS | Healthcare Common Procedure Coding System |
| HHA | Home health agency |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) |
| HIT | Health information technology |
| HITECH | Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the Recovery Act, together with Title XIII of Division A of the Recovery Act) |
| HPSA | Health Professional Shortage Area |
| ICD | International Classification of Diseases |
| IMRT | Intensity Modulated Radiation Therapy |
| IOM | Internet-only Manual |
| IPCI | Indirect practice cost index |
| IPPS | Inpatient prospective payment system |
| IWPUT | Intra-service work per unit of time |
| MAC | Medicare Administrative Contractor |
| MCTRJCA | Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96) |
| MedCAC | Medicare Evidence Development and Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee (MCAC)) |
| MedPAC | Medicare Payment Advisory Commission |
| MEI | Medicare Economic Index |
| MIEA-TRHCA | Medicare Improvements and Extension Act of 2006 (that is, Division B of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109-432) |

| | |
|---|---|
| MIPPA | Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) |
| MMA | Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) |
| MMEA | Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309) |
| MMSEA | Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110-173) |
| MP | Malpractice |
| MPPR | Multiple procedure payment reduction |
| MQSA | Mammography Quality Standards Act of 1992 (Pub. L. 102-539) |
| NP | Nurse practitioner |
| NPP | Nonphysician practitioner |
| OACT | [CMS] Office of the Actuary |
| OBRA | Omnibus Budget Reconciliation Act (Pub. L. 101-239) |
| OIG | [HHS] Office of Inspector General |
| PA | Physician assistant |
| PC | Professional component |
| PE | Practice expense |
| PE/HR | Practice expense per hour |
| PERC | Practice Expense Review Committee |
| PFS | Physician Fee Schedule |
| PGP | [Medicare] Physician Group Practice |
| PLI | Professional liability insurance |
| PPS | Prospective payment system |
| PQRS | Physician Quality Reporting System |
| PRA | Paperwork Reduction Act |
| PPTRA | Physician Payment and Therapy Relief Act of 2010 (Pub. L. 111-286 |

| | |
|---|---|
| PVBP | Physician and Other Health Professional Value-Based Purchasing Workgroup |
| RAC | [Medicare] Recovery Audit Contractor |
| RFA | Regulatory Flexibility Act |
| RIA | Regulatory impact analysis |
| RVU | Relative value unit |
| SBRT | Stereotactic body radiation therapy |
| SGR | Sustainable growth rate |
| TC | Technical component |
| TIN | Tax identification number |
| TPTCCA | Temporary Payroll Tax Cut Continuation Act of 2011(Pub. L.112-78) |
| TRHCA | Tax Relief and Health Care Act of 2006 (Pub. L. 109-432) |
| VBP | Value-based purchasing |

**Addenda Available Only Through the Internet on the CMS Website**

In the past, the Addenda referred to throughout the preamble of our annual PFS proposed and final rules with comment period were included in the printed **Federal Register**. However, effective with the CY 2012 PFS proposed rule, the PFS Addenda no longer appear in the **Federal Register**. Instead these Addenda to the annual proposed and final rules with comment period will be available only through the Internet. 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 Website 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 2013 PFS proposed rule with comment period, refer to item CMS–1590–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this proposed rule with

comment period and posted on the CMS Website identified above should contact Corinne Axelrod at (410) 786–5620.

**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 2011 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 2013. It also would implement provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it would implement statutory changes regarding the termination of non-random prepayment review.

#### 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) and the relative resources used in furnishing a service. The Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice (MP) expense. In this major proposed rule, we propose payment rates for CY 2013 for the PFS, payments for Part B drugs, 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. It also proposes to implement provisions of the Affordable

Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items, and by removing certain regulations regarding the termination of non-random prepayment review. It also proposes new claims-based data reporting requirements for therapy services to implement a provision in the Middle Class Tax Relief and Jobs Creation Act (MCTRCA). In addition, this rule proposes:

● Potentially Misvalued Codes to be Evaluated.

● Additional Multiple Procedure Payment Reductions (MPPR).

● Expanding Medicare Telehealth Services.

● Regulatory Changes regarding Payment for Technical Component of Certain Physician Pathology Services to Conform to Statute.

● Primary Care and Care Coordination Service.

● Payment rates for Newly Covered Preventive Services.

● Definition of Anesthesia and Related Care in the Certified Registered Nurse Anesthetists Benefit.

● Ordering Requirements for Portable X-ray Services.

● Updates to the Ambulance Fee Schedule.

● Part B Drug Payment Rates.

● Ambulance Coverage-Physician Certification Statement.

●Updating the--

++ Physician Compare Website.

++ Physician Quality Reporting System.

++ Electronic Prescribing (eRx) Incentive Program.

++ Medicare Shared Savings Program.

● Providing Budget Neutrality Discussion on the Chiropractic Demonstration.

- Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program.
- Medicare Coverage of Hepatitis B Vaccine.
- Updating Existing Standards for e-prescribing under Medicare Part D and Lifting the LTC Exemption.

3. Summary of Costs and Benefits

The statute requires that we establish by regulation each year payment amounts for all physicians' service. These payment amounts are required to be adjusted to reflect the variations in the costs of providing services in different geographic areas. The statute also 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.

Several proposed changes would affect the specialty distribution of Medicare expenditures. This proposed rule reflects the Administration's priority on improving payment for primary care services. Overall, payments for primary care specialties would increase and payments to select other specialties would decrease due to several changes in how we propose to calculate payments for CY 2013. Primary care payments would increase because of a proposed payment for managing a beneficiary's care when the beneficiary is discharged from an inpatient hospital, a SNF, an outpatient hospital observation, partial hospitalization services, or a community mental health center. Primary care payments also would increase due to redistributions from proposed reductions in payments for other specialties. Because of the budget-neutral nature of this system, proposed decreases in payments in one service result in proposed increases in payments in others.

Payments to primary care specialties are also impacted by the completion of the 4-year

transition to new PE RVUs using the new Physician Practice Information Survey (PPIS) data that was adopted in the CY 2010 PFS final rule with comment period. The projected impacts of using the new PPIS data are generally consistent with the impacts discussed in the CY 2012 final rule with comment period (76 FR 72452).

Proposed changes in how we calculate payment when certain services are furnished together would result in reductions in total payments projected to cardiologists and ophthalmologists. Capital-intensive specialties are projected to decrease due to proposed changes in how the interest rate used in the PE calculation is estimated. Also, under our potentially misvalued codes initiative, , we propose to adjust the payment rates for two common radiation oncology treatment delivery methods, intensity-modulated radiation treatment (IMRT), and stereotactic body radiation therapy (SBRT) to reflect more realistic time projections based upon publicly available data. The combined effect of the PPIS transition and the latter two proposals would be a reduction in payments to radiation therapy centers and radiation oncology.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, "Payment for Physicians' Services." The Act requires that CMS make payments under the PFS using national uniform relative value units (RVUs) based on the relative resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, PE, and MP expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges. We note that throughout this proposed rule, unless otherwise noted, the term "practitioner" is used to describe both physicians and nonphysician practitioners (such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, psychologists, or clinical social workers) who are permitted to bill Medicare under the PFS for their services.

1. Development of the Relative Value System

a. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101-239), and OBRA 1990, (Pub. L. 101-508). The final rule published on November 25, 1991 (56 FR 59502) set forth the fee schedule for payment for physicians' services beginning January 1, 1992. Initially, only the physician work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges.

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 in a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes for 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.

Section 1848(b)(2)(B) of the Act specifies that the RVUs for anesthesia services are based on RVUs from a uniform relative value guide, with appropriate adjustment of the conversion factor (CF), in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. We established a separate CF for anesthesia services, and we continue to utilize time units as a factor in determining payment for these services. As a result, there is a separate payment methodology for anesthesia services.

We establish physician 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 Relative Value Units (PE RVUs)

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 to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs.

Section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), amended section 1848(c)(2)(C)(ii) of the Act to delay 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 charge-based PE RVUs to 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 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, resource-based PE RVUs did not become fully effective until 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. The CPEP data were collected from panels of physicians, practice administrators, and nonphysician health professionals (for example, registered nurses (RNs)) nominated by physician specialty societies and other groups. The CPEP panels identified the direct inputs required for each physicians' service. (We have since refined and revised these inputs based on recommendations from the AMA RUC.) The SMS data provided aggregate specialty-specific information on hours worked and PEs.

Separate PE RVUs are established for procedures that can be furnished in both a nonfacility setting, such as a physician's office, and a facility setting, such as a hospital outpatient department (HOPD). The difference between the facility and nonfacility RVUs reflects the fact that a facility typically receives separate payment from Medicare for its costs of

furnishing the service, apart from payment under the PFS. The nonfacility RVUs reflect all of the direct and indirect PEs of furnishing a particular service.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) 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 in CY 2010. Direct PE RVUs were calculated for CY 2013 using this methodology, unless otherwise noted.

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). For this update, we used the Physician Practice Information Survey (PPIS) conducted by the AMA. The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) using a survey instrument and methods highly consistent with those of the SMS and the supplemental surveys used prior to CY 2010. We note that in CY 2010, for oncology, clinical laboratories, and independent diagnostic testing facilities (IDTFs), we continued to use the supplemental survey data to determine PE/HR values

(74 FR 61752). Beginning in CY 2010, we provided for a 4-year transition for the new PE RVUs using the updated PE/HR data. In CY 2013, the final year of the transition, PE RVUs are calculated based on the new data.

c. Resource-Based Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act requires 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 were 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.

The First Five-Year Review of Work RVUs was published on November 22, 1996 (61 FR 59489) and was effective in 1997. The Second Five-Year Review of Work RVUs was published in the CY 2002 PFS final rule with comment period (66 FR 55246) and was effective in 2002. The Third Five-Year Review of Work RVUs was published in the CY 2007 PFS final rule with comment period (71 FR 69624) and was effective on January 1, 2007. The Fourth Five-Year Review of Work RVUs was published in the CY 2012 PFS final rule with comment period (76 FR 73026).

Initially refinements to the direct PE inputs relied on input from the AMA RUC-established the Practice Expense Advisory Committee (PEAC). Through March 2004, the PEAC provided recommendations to CMS for more than 7,600 codes (all but a few hundred of the codes included in the AMAs Current Procedural Terminology (CPT) codes). As part of the

CY 2007 PFS final rule with comment period (71 FR 69624), we implemented a new bottom-up methodology for determining resource-based PE RVUs and transitioned the new methodology over a 4-year period. A comprehensive review of PE was undertaken prior to the 4-year transition period for the new PE methodology from the top-down to the bottom-up methodology, and this transition was completed in CY 2010. In CY 2010, we also incorporated the new PPIS data to update the specialty-specific PE/HR data used to develop PE RVUs, adopting a 4 year transition to PE RVUs developed using the PPIS data.

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

In the CY 2005 PFS final rule with comment period (69 FR 66236), we implemented the first Five-Year Review of the MP RVUs (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). The second Five-Year Review and update of resource-based malpractice RVUs was published in the CY 2010 PFS final rule with comment period (74 FR 61758) and was effective in 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 the following categories: (1) codes and families of codes for which there has been the fastest growth; (2) codes or families of codes that have experienced substantial changes in PEs; (3) codes that are recently

established for new technologies or services; (4) multiple codes that are frequently billed in conjunction with furnishing a single service; (5) codes with low relative values, particularly those that are often billed multiple times for a single treatment; (6) codes which have not been subject to review since the implementation of the fee schedule (the so-called 'Harvard valued codes'); and (7) other codes determined to be appropriate by the Secretary.

e. Application of Budget Neutrality to Adjustments of RVUs

Budget neutrality (BN) typically requires that expenditures not increase or decrease as a result of changes or revisions to policy. However, section 1848(c)(2)(B)(ii)(II) of the Act requires adjustment only if the change in expenditures resulting from the annual revisions to the PFS exceeds a threshold amount. Specifically, adjustments in RVUs for a year may not cause total PFS payments to differ by more than $20 million from what they would have been if the adjustments were not made. In accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs would 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.

2. Components of the Fee Schedule Payment Amounts

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). The GPCIs reflect the relative costs of physician work, PE, and MP in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated by CMS' Office of the Actuary (OACT).

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

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

3. Most Recent Changes to the Fee Schedule

The CY 2012 PFS final rule with comment period (76 FR 73026) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2011 interim RVUs and implemented interim RVUs for new and revised codes for CY 2012 to ensure that our payment systems are updated to reflect changes in medical practice and the relative values of services. The CY 2012 PFS final rule with comment period also addressed other policies including certain statutory provisions including provisions of the Affordable Care Act and the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

In the CY 2012 PFS final rule with comment period, we announced the following for CY 2012: the total PFS update of -27.4 percent; the initial estimate for the sustainable growth rate (SGR) of -16.9 percent; and the conversion factor (CF) of $24.6712. These figures were calculated based on the statutory provisions in effect on November 1, 2011, when the CY 2012 PFS final rule with comment period was issued.

A correction notice was issued (77 FR 227) to correct several technical and typographical errors that occurred in the CY 2012 PFS final rule with comment period.

On December 23, 2011, the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) (Pub. L. 112-78) was signed into law. Section 301 of the TPTCCA specified a zero percent update to the PFS claims from January 1, 2012 through February 29, 2012. As a result, the CY 2012 PFS conversion factor was revised to $34.0376 for claims with dates of service on or after January 1, 2012 through February 29, 2012. In addition, TPTCCA extended several provisions affecting Medicare services furnished on or after January 1, 2012 through February 29, 2012, including:

- Section 303 - the 1.0 floor on the physician work geographic practice cost index;
- Section 304 - the exceptions process for outpatient therapy caps;
- Section 305 - the payment to independent laboratories for the TC of physician

pathology services furnished to certain hospital patients, and

- Section 307 - the five percent increase in payments for mental health services.

On February 22, 2012, the MCTRJCA was signed into law. Section 3003 extended the zero percent PFS update to the remainder of CY 2012. As a result of the MCTRJCA, the CY 2012 PFS CF was maintained as $34.0376 for claims with dates of service on or after March 1, 2012 through December 31, 2012. In addition:

- Section 3004 of MCTRJCA extended the 1.0 floor on the physician work geographic practice cost index through December 31, 2012;
- Section 3006 continued payment to independent laboratories for the TC of physician pathology services furnished to certain hospital patients through June 30, 2012; and
- Section 3005 extended the exceptions process for outpatient therapy caps through CY 2012 and made several other changes related to therapy claims and caps.

On March 1, 2012, as required by Section 1848(d)(1)(E) of the Act, we submitted to the Medicare Payment Advisory Committee (MedPAC) an estimate of the SGR and conversion factor applicable to Medicare payments for physicians' services for CY 2013. The actual values used to compute physician payments for CY 2013 will be based on later data and are scheduled to be published by November 1, 2012 as part of the CY 2013 PFS final rule.

## II. Provisions of the Proposed Rule

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

#### 1. Overview

Practice expense (PE) is the portion of the resources used in furnishing the 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, required 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 use a "bottom-up" approach to determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing each 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 bottom-up 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), which was expanded (relative to the SMS) to include nonphysician practitioners (NPPs) paid under the PFS.

The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs using a consistent 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 healthcare professional groups. We believe the PPIS is the most comprehensive source of PE

survey information available to date. Therefore, we used the PPIS data to update the PE/HR data for almost all of the Medicare-recognized specialties that participated in the survey for the CY 2010 PFS.

When we began using the PPIS data beginning 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 finalized a 4-year transition (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.

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

We 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 these data with Medicare-recognized specialty data. Similarly, we do not use the PPIS data for sleep medicine since there is not a full year of Medicare utilization data for that specialty.

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 medical oncology, independent laboratories, and IDTFs were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

Previously, we have 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 use the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for 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).

There were five specialties whose utilization data were newly incorporated into ratesetting for CY 2012. In accordance with the final policies adopted in the CY 2012 final rule with comment period (76 FR 73036), we use proxy PE/HR values for these specialties by crosswalking values from other, similar specialties as follows: Speech Language Pathology from Physical Therapy; Hospice and Palliative Care from All Physicians; Geriatric Psychiatry from Psychiatry; Intensive Cardiac Rehabilitation from Cardiology, and Certified Nurse Midwife from Obstetrics/gynecology.

For CY 2013, there are two specialties whose utilization data will be newly incorporated into ratesetting. We are proposing to use proxy PE/HR values for these specialties by crosswalking values from other specialties that furnish similar services as follows: Cardiac Electrophysiology from Cardiology; and Sports Medicine from Family Practice. These proposed changes are reflected in the "PE HR" file available on the CMS Website under the supporting data files for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), CY 2013 is the final year of the 4-year transition to the PE RVUs calculated using the PPIS data. Therefore, the CY 2013 proposed PE RVUs were developed based entirely on the PPIS data, with the exceptions described in this section.

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 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. For example, if the direct portion of the PE RVUs for a given service was 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 6.00 since 2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00.

- We then 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 6.00 plus 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) 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.

- We next incorporate the specialty-specific indirect PE/HR data into the calculation. As a relatively extreme example for the sake of simplicity, assume in our previous example that, 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. In this case, 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 Medicare makes a separate payment to the facility for its costs of furnishing a service, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

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), each of which 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 component 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 components, TCs, and PCs; that is, we apply the same weighted average indirect percentage

factor to allocate indirect expenses to the global components, 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 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.

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 components.

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 1, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).

- The second part is either the work RVUs, clinical PE RVUs, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the 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 components, 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 component.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs. This final BN adjustment is required in order 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.)

(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 |

| Specialty Code | Specialty Description |
|---|---|
| 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 |

We are proposing to calculate the specialty mix for low volume services (fewer than 100 billed services in the previous year) using the same methodology we use for non-low volume services. We previously have used the survey data from the dominant specialty for these low volume services. However, because these services have such low utilization, the dominant specialty tends to change from year to year. We are proposing to calculate a specialty mix for these services rather than use the dominant specialty in order to smooth year-to-year fluctuations in PE RVUs due to changes in the dominant specialty.

- 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 Medicare 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 |
| 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) including the proposed ophthalmology and cardiovascular diagnostic services MPPR discussed in section II.B.4. of this proposed rule. 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 budget-neutrality calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These multiple procedure payment reductions are not included in the development of the relative value units.

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

- Work RVUs: The setup file contains the work RVUs from this proposed rule.

(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 = 0.5 is the standard equipment utilization assumption; 0.75 for certain expensive diagnostic imaging equipment (see 74 FR 61753 through 61755 and section II.A.3. of the CY 2011 PFS final rule with comment period).

price = price of the particular piece of equipment.

interest rate = sliding scale (see proposal below)

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

maintenance = factor for maintenance; 0.05.

The interest rate we have previously used was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). In the CY 2012 proposed rule (76 FR 42783), we solicited comment regarding reliable data on current prevailing loan rates for small

businesses. In response to that request, the AMA RUC recommended that rather than applying the same interest rate across all equipment, CMS should consider a "sliding scale" approach which varies the interest rate based on the equipment cost, useful life, and SBA (Small Business Administration) maximum interest rates for different categories of loan size and maturity. The maximum interest rates for SBA loans are as follows:

- Fixed rate loans of $50,000 or more must not exceed Prime plus 2.25 percent if the maturity is less than 7 years, and Prime plus 2.75 percent if the maturity is 7 years or more.
- For loans between $25,000 and $50,000, maximum rates must not exceed Prime plus 3.25 percent if the maturity is less than 7 years, and Prime plus 3.75 percent if the maturity is 7 years or more.
- For loans of $25,000 or less, the maximum interest rate must not exceed Prime plus 4.25 percent if the maturity is less than 7 years, and Prime plus 4.75 percent, if the maturity is 7 years or more.

The current Prime rate is 3.25 percent.

Based on that recommendation, for CY 2013, we are proposing to use a "sliding scale" approach based on the current SBA maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment). Additionally, we are proposing to update this assumption through annual PFS rulemaking to account for fluctuations in the Prime rate and/or changes to the SBA's formula to determine maximum allowed interest rates.

The effects of this proposal on direct equipment inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

Additionally, we note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

## TABLE 3: CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

| | Step | Source | Formula | 99213 Office visit, est nonfacility | 33533 CABG, arterial, single facility | 71020 Chest x-ray nonfacility | 71020-TC Chest xray nonfacility | 71020-26 Chest xray nonfacility | 93000 ECG, complete nonfacility | 93005 ECG, tracing nonfacility | 93010 ECG, report nonfacility |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **(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 | 7.34 | 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 | 85.45 | 16.38 | 16.38 | 0.00 | 7.42 | 7.42 | 0.00 |
| **(5) Direct adjustment (Dir. Adj).** | Steps 2-4 | See footnote* | | 0.58 | 0.58 | 0.58 | 0.58 | 0.58 | 0.58 | 0.58 | 0.58 |
| **(6) Adjusted Labor** | Steps 2-4 | =Lab * Dir Adj | =(1)*(5) | 7.68 | 44.68 | 3.31 | 3.31 | 0.00 | 3.53 | 3.53 | 0.00 |
| **(7) Adjusted Supplies** | Steps 2-4 | = Sup * Dir Adj | =(2)*(5) | 1.72 | 4.23 | 1.95 | 1.95 | 0.00 | 0.69 | 0.69 | 0.00 |
| **(8) Adjusted Equipment** | Steps 2-4 | = Eqp * Dir Adj | =(3)*(5) | 0.10 | 0.34 | 4.17 | 4.17 | 0.00 | 0.06 | 0.06 | 0.00 |
| **(9) Adjusted direct** | Steps 2-4 | | =(6)+(7)+(8) | 9.50 | 49.25 | 9.44 | 9.44 | 0.00 | 4.28 | 4.28 | 0.00 |
| **(10) Conversion Factor (CF)** | Step 5 | PFS | | 34.0376 | 34.0376 | 34.0376 | 34.0376 | 34.0376 | 34.0376 | 34.0376 | 34.0376 |
| **(11) Adj. labor cost converted** | Step 5 | =(Lab * Dir Adj)/CF | =(6)/(10) | 0.23 | 1.31 | 0.10 | 0.10 | 0.00 | 0.10 | 0.10 | 0.00 |
| **(12) Adj. supply cost converted** | Step 5 | =(Sup * Dir Adj)/CF | =(7)/(10) | 0.05 | 0.12 | 0.06 | 0.06 | 0.00 | 0.02 | 0.02 | 0.00 |

| | Step | Source | Formula | 99213 Office visit, est nonfacility | 33533 CABG, arterial, single facility | 71020 Chest x-ray nonfacility | 71020-TC Chest xray nonfacility | 71020-26 Chest xray nonfacility | 93000 ECG, complete nonfacility | 93005 ECG, tracing nonfacility | 93010 ECG, report nonfacility |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **(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) | 0.28 | 1.45 | 0.28 | 0.28 | 0.00 | 0.13 | 0.13 | 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) | 0.82 | 6.76 | 0.68 | 0.68 | 0.00 | 0.31 | 0.31 | 0.00 |
| **(20) Ind. Alloc. Formulas (2nd part).** | Step 8 | See Step 8 | | (15) | (15) | (15+11) | (11) | (15) | (15+11) | (11) | (15) |
| **(21) Ind. Alloc. (2nd part).** | Step 8 | | See (20) | 0.97 | 33.75 | 0.32 | 0.10 | 0.22 | 0.27 | 0.10 | 0.17 |
| **(22) Indirect Allocator (1st + 2nd)** | Step 8 | | =(19)+(21) | 1.79 | 40.51 | 1.00 | 0.78 | 0.22 | 0.59 | 0.42 | 0.17 |
| **(23) Indirect Adjustment (Ind. Adj.)** | Steps 9-11 | See footnote** | | 0.40 | 0.40 | 0.40 | 0.40 | 0.40 | 0.40 | 0.40 | 0.40 |
| **(24) Adjusted indirect allocator** | Steps 9-11 | =Ind Alloc * Ind Adj | | 0.72 | 16.25 | 0.40 | 0.31 | 0.09 | 0.23 | 0.17 | 0.07 |
| **(25) Ind. Practice Cost Index (IPCI)** | Steps 12-16 | See Steps 12 - 16 | | 1.12 | 0.79 | 0.92 | 0.92 | 0.92 | 0.94 | 0.94 | 0.94 |
| **(26) Adjusted Indirect** | Step 17 | = Adj.Ind Alloc * PCI | =(24) * (25) | 0.80 | 12.76 | 0.37 | 0.29 | 0.08 | 0.22 | 0.16 | 0.06 |

| | Step | Source | Formula | 99213 Office visit, est nonfacility | 33533 CABG, arterial, single facility | 71020 Chest x-ray nonfacility | 71020-TC Chest xray nonfacility | 71020-26 Chest xray nonfacility | 93000 ECG, complete nonfacility | 93005 ECG, tracing nonfacility | 93010 ECG, report nonfacility |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **(28) PE RVU** | Step 18 | =(Adj Dir + Adj Ind) * budn | =((14)+(26)) * budn | 1.08 | 14.19 | 0.64 | 0.56 | 0.08 | 0.34 | 0.28 | 0.06 |

Note: PE RVUs in table 2, 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]
Note: The use of any particular conversion factor (CF) in Table 3 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 specific CY 2013 proposals and changes related to direct PE inputs for specific services. We note that we will address comments on the interim direct PE inputs established in the CY 2012 PFS final rule with comment period in the CY 2013 PFS final rule.

a. Equipment Minutes for Interrogation Device Evaluation Services

It has come to our attention that the pacemaker follow-up system (EQ138) associated with two interrogation device management service codes does not have minutes allocated in the direct PE input database. Based on our analysis of these services, we believe that 10 minutes should be allocated to the equipment for each of the following CPT codes: 93294 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim physician analysis, review(s) and report(s)), and 93295 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable cardioverter-defibrillator system with interim physician analysis, review(s) and report(s)). Therefore, we are proposing to modify the direct PE input database to allocate 10 minutes to the pacemaker follow-up system for CPT codes 93294 and 93295.

The proposed CY 2013 direct PE input database reflects these changes and is available on the CMS Website under the supporting data files for the CY 2013 PFS proposed rule with comment period at http://www.cms.gov/PhysicianFeeSched/. We also note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

b. Clinical Labor for Pulmonary Rehabilitation Services (HCPCS Code G0424)

It has come to our attention that the direct PE input database includes 15 minutes of clinical labor time in the nonfacility setting allocated for a CORF social worker/psychologist (L045C) associated with HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day). Based on our analysis of this service, we believe that these 15 minutes should be added to the 15 minutes currently allocated to the Respiratory Therapist (L042B) associated with this service. Therefore, we are proposing to modify the direct PE input database to allocate 15 additional minutes to the Respiratory Therapist (L042B) (for a total of 30 minutes) and delete the CORF social worker/psychologist (L045C) associated with HCPCS code G0424.

The proposed CY 2013 direct PE input database reflects these changes and is available on the CMS Website under the supporting data files for the CY 2013 PFS proposed rule with comment period at http://www.cms.gov/PhysicianFeeSched/. We also note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

c. Transcranial Magnetic Stimulation Services.

For CY 2011, the CPT Editorial Panel converted Category III CPT codes 0160T and 0161T to Category I status (CPT codes 90867 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), and 90868 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session)), which were contractor priced on the PFS. For CY 2012, the CPT Editorial Panel modified CPT codes 90867 and 90868, and created CPT code 90869 ((Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management.)

In the CY 2012 PFS final rule with comment period, we established interim final values based on refinement of RUC recommended work RVUs, direct PE inputs, and malpractice risk factor crosswalks for these services (76 FR 73201).

Subsequent to the development of interim final PE RVUs, it came to our attention that the application of our usual PE methodology resulted in anomalous PE values for these services. As we explain in section II.A.2.c.2 of this proposed rule with comment period, for a given service, we use the direct costs associated with a service (clinical staff, equipment, and supplies) 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.

For services almost exclusively furnished by one specialty, the average percentage of indirect costs relative to direct costs would ordinarily be used to determine the initial indirect allocator. For specialties that typically incur significant direct costs relative to indirect costs, the initial indirect allocator for their services is generally lower than for the specialties that typically incur lower direct costs relative to indirect costs. Relative to direct costs, the methodology generally allocates a greater proportion of indirect PE to services furnished by psychiatrists, for example, than to services furnished by specialties that typically incur significant direct costs, such as radiation oncologists. In the case of the TMS, however, the direct costs incurred by psychiatrists reporting the codes far exceed the direct costs typical to any other service predominantly furnished by psychiatrists. This drastic difference in the direct costs of TMS relative to most other services furnished by psychiatrists results in anomalous PE values since code-level indirect PE allocation relies on typical resource costs for the specialties that furnish the service. In other words, the amount of indirect PE allocated to TMS services is based on the proportion of indirect expense to direct expense that is typical of other psychiatric services, and

is not on par with other services that require similar investments in capital equipment and high-cost, disposable supplies.

Historically, we have contractor-priced services with resource costs that cannot be appropriately valued within the generally applicable PE methodology used to price services across the PFS. Because there is no mechanism to develop appropriate payment rates for these services within our current methodology, we are proposing to contractor price these codes for CY 2013.

d. Spinal Cord Stimulation Trial Procedures in the Nonfacility Setting

Stakeholders have recently brought to our attention that CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) is frequently furnished in the physician office setting but is not priced in that setting. We note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition. However, because these services are being furnished in the nonfacility setting, we believe that CPT code 63650 should be reviewed to establish appropriate nonfacility inputs. We propose to review CPT code 63650 and request recommendations from the AMA RUC and other public commenters on the appropriate physician work RVUs (as measured by time and intensity), and facility and nonfacility direct PE inputs for this service. We understand that disposable leads comprise a significant resource cost for this service and are currently separately reportable to Medicare for payment purposes when the service is furnished in the physician office setting. Disposable medical supplies are not considered prosthetic devices paid under the Durable Medical Equipment, Prosthetic/Orthotic, and Supplies (DMEPOS) fee schedule and generally are incorporated as nonfacility direct PE

inputs to PE RVUs. We seek comment on establishing nonfacililty PE RVUs for CPT code 63650.

B. Potentially Misvalued Codes Under the Physician Fee Schedule

1. Valuing Services Under the PFS

To value 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; practice expense (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."

As discussed in detail in sections I.B.1.b. and I.B.1.c. of this proposed rule, the statute also defines the PE and malpractice components and provides specific guidance in the calculation of the RVUs for each of these components. Section 1848(c)(1)(B) of the Act defines the PE component as "the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses." Section 1848(c)(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. On March 23, 2010, the Affordable Care Act was enacted, further requiring the Secretary to periodically identify and

review potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being potentially misvalued. 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 I.B.1.a. 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 data sources, 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), 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 on the PFS

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 for a number of reasons: For example, MedPAC stated, “when a new service is added to the PFS, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it." That is, the amount of physician work needed to furnish an existing service may decrease as physicians build experience furnishing that service. 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 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 seven categories as follows:

- 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 PFS (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) which may include consolidation of individual services into bundled codes for payment under the PFS.

In addition to these requirements, section 3003 (b)(1) of the Middle Class Tax Cut and Job Creation Act of 2012 (Pub. L. 112-96), requires that the Secretary conduct a study that examines options for bundled or episode-based payment to cover physicians' services currently paid under the PFS under section 1848 of the Act for one or more prevalent chronic conditions or episodes of care for one or more major procedures. In conducting the study, the Secretary shall consult with medical professional societies and other relevant stakeholders. Additionally, the study shall include an examination of related private payer payment initiatives. This section also requires that not later than January 1, 2013, the Secretary submit to certain committees of the Congress a report on the study. The report shall include recommendations on suitable alternative payment options for services paid under the PFS and on associated implementation requirements.

Bundling is one method for structuring payment that can improve payment accuracy and efficiency, assuming the bundling proposal has considered the payment system, context, and included services. Current work on bundling to date has targeted specific codes and sets of codes. Specifically, our ongoing work identifying, reviewing, and validating the RVUs of

potentially misvalued services on the PFS will support the development of this report. As detailed above, through the potentially misvalued codes initiative we are currently identifying for review codes that are frequently billed together and codes with low relative values billed in multiples. Many of the codes identified through these screens have been referred to the CPT Editorial Panel for the development of a comprehensive or bundled code, and several bundled codes have already been created and valued. Additionally, in section II.B.2.d. of this CY 2013 PFS proposed rule, we discuss improving the value of the global surgical package and request public comment on methods of obtaining accurate and current data on E/M services furnished as part of global surgical procedures. This information on measuring post-operative work in our current payment bundles also will inform our report to the Congress. We will continue to examine options for bundled or episode-based payments and will include our recommendations and implementation options in our report to the Congress submitted no later than January 1, 2013.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

In accordance with 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, identifies potentially misvalued codes for review, and through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule, other

individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,000 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.

Our prior reviews of codes under the potentially misvalued codes initiative have included codes in all seven categories specified in section 1848(c)(2)(K)(ii) of the Act, listed above. 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 last year's PFS proposed rule (CY 2012), we identified potentially misvalued codes in the category of "Other codes determined to be appropriate by the Secretary," referring a list of the highest PFS expenditure services, by specialty, that had not been recently reviewed (76 FR 73059 through73068). In the CY 2012 final rule with comment period we finalized 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 to replace the Five-Year review process (76 FR 73058 through 73059). Below we discuss proposals that support our continuing efforts to appropriately identify, review, and adjust values for potentially misvalued codes.

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). In CY 2012 we intend to enter into a contract to assist us in validating RVUs of potentially misvalued codes that will explore a model for the validation of physician work under the PFS, both for new and existing services. We plan to discuss this model further in future rulemaking.

d. Improving the Valuation of the Global Surgical Package

(1) Background

We applied the concept of payment for a global surgical package under the PFS at its inception on January 1, 1992 (56 FR 59502). For each global surgical procedure, we establish a single payment, which includes payment for a package of all related services typically furnished by the surgeon furnishing the procedure during the global period. Each global surgery is paid on

the PFS as a single global surgical package. Each global surgical package payment rate is based on the work necessary for the typical surgery and related pre- and post-operative work. The global period may include 0, 10, or 90 days of post-operative care, depending on the procedure. For major procedures, those with a 90-day global period, the global surgical package payment also includes the day prior to the day of surgery.

Some global surgical packages have been valued by adding the RVU of the surgical procedure and all pre- and post-operative evaluation and management (E/M) services included in the global period. Others have been valued using magnitude estimation, in which case, the overall RVU for the surgical package was determined without factoring in the specific RVUs associated with the E/M services in the global period. The number and level of E/M services identified with a global surgery payment are based on the typical case. Even though a surgical package may have been developed with several E/M services included, a physician is not required to furnish each pre- or post-operative visit to bill for the global surgical package.

Similar to other bundled services on the PFS, when a global surgery code is billed, the bundled pre- and post-operative care is not separately payable; surgeons or other physician billing a surgical procedure, cannot separately bill for the E/M services that are included in the global surgical package.

(2) Measuring Post-Operative Work

The use of different methodologies for valuing global surgical packages since 1992 has created payment rates with a wide range of E/M services included within the post-operative period. This is especially true among those with 90-day global periods. More recently reviewed codes tend to have fewer E/M services in the global period, and the work RVUs of those E/M services are often accounted for in the value for the global surgical package. The value of less

recently reviewed global surgeries frequently do not appear to include the full work RVUs of each E/M service in the global surgical package, and the numbers of E/M services included in the post-operative period can be inconsistent within a family of procedures. For example, there is significant variation in the number and level of E/M services included in two transplantation procedures in Table 4. Pre-, intra-, and post-operative times, including the number of post-operative visits, for each global surgical package can be found in the physician time file on the CMS Website at http://www.cms.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=descending&itemID=CMS1253669&intNumPerPage=10.

**TABLE 4: Transplantation Procedures Showing a Significant Range in the Number of Included E/M Services**

| CPT Code | Short Descriptor | Work RVU | E/M services included in global period | | | | Total E/M Work RVU |
|---|---|---|---|---|---|---|---|
| | | | 99213 | 99231 | 99238 | 99291 | |
| 50360 | Transplantation of kidney | 40.90 | 9 | 12 | 1 | 10 | 64.13 |
| 47135 | Transplantation of liver | 83.64 | 7 | 0 | 0 | 0 | 6.79 |

In 2005, the HHS Office of Inspector General (OIG) examined whether global surgical packages are appropriately valued. In its report on eye and ocular surgeries, "National Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005" (A-05-07-00077), the OIG reviewed a sample of 300 eye and ocular surgeries, and counted the actual number of face-to-face services in the surgeons' medical records to establish whether the surgeon furnished post-operative E/M services. The OIG findings show that surgeons typically furnished fewer E/M services in the post-operative period than were identified with the global surgical package payment for each procedure. A smaller percentage of surgeons furnished more E/M services than were identified with the global surgical package payment. The OIG could only review the number of face-to-face services and was not

able to review the level of E/M services that the surgeons furnished due to a lack of documentation in surgeons' medical records. The OIG concluded that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures.

Following the 2005 report, the OIG continued to investigate E/M services furnished during the global surgical period. In May 2012, the OIG published a report titled "Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided" (A-05-09-00053). For this investigation, the OIG sampled 300 musculoskeletal global surgeries and again found that, for the majority of sampled surgeries, physicians furnished fewer E/M services than were identified as part of the global period for that service. Once again, a smaller percentage of surgeons furnished more E/M services than were identified with the global surgical package payment. The OIG concluded that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures.

In both reports, the OIG recommended that we adjust the number of E/M services identified with the global surgical payments to reflect the number of E/M services that are actually being furnished. Under the PFS, we do not ask surgeons to report bundled services on their claim when billing for the global surgical package as we do providers furnishing bundled services under other Medicare payment systems. Since it is not necessary for a surgeon to identify the level and code of the E/M services actually furnished during the global period, there is very limited documentation on the frequency or level of post-operative services. Without sufficient documentation, a review of the medical record cannot accurately determine the number or level of E/M services furnished in the post-operative period.

As noted above, section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act), which essentially codified the potentially misvalued codes initiative, requires that the Secretary identify and review potentially misvalued services with an emphasis on several categories, and recognizes the Secretary's discretion to identify additional potentially misvalued codes. Several of the categories of potentially misvalued codes support better valuation of global surgical package codes. We have made efforts to prioritize the review of RVUs for services on the PFS that have not been reviewed recently or for services where there is a potential for misuse. 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 utilization greater than 30,000 (Harvard-valued—Utilization > 30,000). In section II.B.3 of this proposed rule, we propose to review Harvard-valued services with annual allowed charges that total at least $10,000,000 (Harvard-valued—Allowed charges ≥$10,000,000), and request recommendations from the AMA RUC and other public commenters on appropriate values for these services.

Of the more than 1,000 identified potentially misvalued codes, just over 650 are surgical services with a global period of 0, 10, or 90 days. We have completed our review of 450 of these potentially misvalued surgical codes. These efforts are important, but we believe the usual review process does not go far enough to assess whether the valuation of global surgical packages reflects the number and level of post-operative services that are typically furnished. To

support our statutory obligation to identify and review potentially misvalued services and to respond to the OIG's concern that global surgical package payments are misvalued, we believe that we should begin gathering more information on the E/M services that are typically furnished with surgical procedures. Information regarding the typical work involved in surgical procedures with a global period is necessary to evaluate whether certain surgical procedures are appropriately valued. While the AMA RUC reviews and recommends RVUs for services on the PFS, we complete our own assessment of those recommendations, and may adopt different RVUs. However, for procedures with a global period, the lack of claims data and documentation restrict our ability to review and assess the appropriateness of their RVUs.

We are seeking comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package. We are especially interested in and invite comments on a claims-based data collection approach that would include reporting E/M services furnished as part of a global surgical package, as well as other valid, reliable, generalizable, and robust data to help us identify the number and level of E/M services typically furnished in the global surgical period for specific procedures. We will carefully weigh all comments received as we consider ways to appropriately review values for global surgical packages.

3. CY 2013 Identification and Review of Potentially Misvalued Services

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule, we finalized a public nomination process for potentially misvalued codes (76 FR 73058). Under the previous Five-Year Reviews, the public nominated potentially misvalued codes for review. To allow for public input and to preserve the public's ability to identify and nominate potentially misvalued codes for review under our annual potentially misvalued codes initiative, we established a process by which the public can submit

codes, along with documentation supporting the need for review, on an annual basis. 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), 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.

Under this newly established process, 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 would evaluate the supporting documentation and assess whether they appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we would publish the list of nominated codes, and indicate whether each nominated code will be reviewed as potentially misvalued.

This year is the first year we are considering codes we received through this public nomination process for potentially misvalued codes. In the 60 days following the release of the CY 2012 PFS final rule with comment period, we received nominations and supporting documentation for review of the codes listed in Tables 5 and 6. A total of 36 CPT codes were nominated. The majority of the nominated codes were codes for which we finalized RVUs in the CY 2012 PFS final rule. That is, the RVUs were interim in CY 2011 and finalized for CY 2012, or proposed in either the Fourth Five-Year Review of Work or the CY 2012 PFS proposed rule and finalized for CY 2012. Under this annual public nomination process, we note that it would be highly unlikely that we would determine that a nominated code is appropriate for review under the potentially misvalued codes initiative if it had been reviewed in the years immediately preceding its nomination since we believe that the best information on the level of physician work and PE inputs already would have been available through that recent review. Nonetheless, we evaluated the supporting documentation for each nominated code to ascertain whether the submitted information demonstrated that the code is potentially misvalued.

**TABLE 5: CPT Codes Nominated as Potentially Misvalued in CY 2012 Final Rule Comment Period: Proposed Action**

| CPT Code | Short Descriptor | Last Reviewed For: | CMS Proposed Action | Regulations.gov comment search |
|---|---|---|---|---|
| 33282 | Implant pat-active ht record | CY 2000 | Review and add nonfacility inputs. Not considered potentially misvalued. | CMS-2011-0131-1422 |
| 33284 | Remove pat-active ht record | CY 2000 | Review and add nonfacility inputs. Not considered potentially misvalued. | CMS-2011-0131-1422 |
| 77336 | Radiation physics consult | CY 2003 (PE Only) | Review as a potentially misvalued code. | CMS-2011-0131-1617 |
| 94762 | Measure blood oxygen level | CY 2010 (PE Only) | Propose revisions in the CY 2013 PFS proposed rule. | CMS-2011-0131-1615; CMS-2011-0131-1412; CMS-2011-0131-1632 |

CPT codes 33282 (Implantation of patient-activated cardiac event recorder) and 33284 (Removal of an implantable, patient-activated cardiac event recorder) were nominated for review as potentially misvalued codes. The commenter asserted that CPT codes 33282 and 33284 are misvalued in the nonfacility setting because these CPT codes currently are only priced in the facility setting even though physicians perform these services in the office setting. The commenter requested that we establish appropriate payment for the services when furnished in a physician office. Specifically, they requested that CMS establish nonfacility PE RVUs for these services. We do not consider the lack of pricing in a particular setting as an indicator of a potentially misvalued code. However, given that these services are now furnished in the nonfacility setting, we believe that CPT codes 33282 and 33284 should be reviewed to establish appropriate nonfacility inputs. We note, as did the commenter, that the valuation of a service under the PFS in a particular setting does not address whether those services and the setting in which they are furnished are medically reasonable and necessary for a patient's medical needs and condition. We propose to review CPT codes 33282 and 33284 and request recommendations from the AMA RUC and other public commenters on the appropriate

physician work RVUs (as measured by time and intensity), and facility and nonfacility direct PE inputs for these services.

Like CPT codes 33282 and 33284, stakeholders have requested that we establish appropriate payment for CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) when furnished in an office setting. This request was not submitted as a potentially misvalued code nomination. However, given that these services are now furnished in the nonfacility setting, we believe CPT code 63650 should be reviewed to establish appropriate nonfacility inputs. Please see section II.A.3 (Changes to Direct Inputs for Specific Services) for a discussion of spinal code stimulation trial procedures in the nonfacility setting.

CPT code 77336 (Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy) was nominated for review as a potentially misvalued code. The commenter asserted that CPT code 77336 is misvalued because changes in the technique for rendering continuing medical physics consultations have resulted in changes to the knowledge required, time, and effort expended, and complexity of technology associated with the tasks performed by the physicist other staff. Additionally the commenter believes that the direct PE inputs no longer accurately reflect the resources used to deliver this service and may be undervalued. CPT code 77336 was last reviewed for CY 2003. After evaluating the detailed supporting information that the commenter provided, we believe there may have been changes in technology and other PE inputs since we last reviewed the service, and that further review is warranted. As such, we propose to review CPT code 77336 as potentially misvalued and request recommendations from the AMA RUC

and other public commenters on the direct PE inputs for this service, and physician work RVUs and direct PE inputs for the other services within this family of CPT codes.

CPT code 94762 (Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)) was nominated for review as a potentially misvalued code. Commenters asserted that CPT code 94762 is misvalued because the time currently allocated to the various direct PE inputs does not accurately reflect current practice. Commenters also asserted that independent diagnostic testing facilities are not appropriately accounted for in the current indirect PE methodology. In response to these stakeholder concerns, we reviewed the PE inputs for CPT code 94762, which was last reviewed for CY 2010. We believe CPT code 94762 is misvalued, and we are proposing changes to the PE inputs for CY 2013. Following clinical review, we believe that the current time allocated to clinical labor and supplies appropriately reflects current practice. However, we believe that 480 minutes (8 hours) of equipment time for the pulse oximetry recording slot and pulse oximeter with printer are more appropriate for this overnight monitoring procedure code. As such, we are proposing this refinement to the direct PE inputs for CPT code 94762 for CY 2013. These proposed adjustments are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

CPT code 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff) was nominated for review as a potentially misvalued code. CPT code 53445 was identified through the site-of-service anomaly potentially misvalued code screen for CY 2008 and is currently interim for CY 2012 and open to public comment. We will consider the content of the potentially misvalued code nomination and supporting

documentation for CPT code 53445 as comments on the interim final value, and will address the comments in the CY 2013 PFS final rule with comment period when we address the final value of the CPT code.

For purposes of CY 2013 rulemaking, we do not consider the other nominated codes, listed in Table 6 to be potentially misvalued because these codes were last reviewed and valued for CY 2012 and the supporting documentation did not provide sufficient evidence to demonstrate that the codes should be reviewed as potentially misvalued for CY 2013 or CY 2014. The supporting documentation for these services generally mirrored the public comments previously submitted, to which CMS has already responded.

**TABLE 6: CPT Codes Nominated as Potentially Misvalued in CY 2012 Final Rule Comment Period: No Further Action Proposed**

| CPT Code | Short Descriptor |
|---|---|
| 28820 | Amputation of toe |
| 28825 | Partial amputation of toe |
| 35188 | Repair blood vessel lesion |
| 35612 | Artery bypass graft |
| 35800 | Explore neck vessels |
| 35840 | Explore abdominal vessels |
| 35860 | Explore limb vessels |
| 36819 | Av fuse uppr arm basilic |
| 36825 | Artery-vein autograft |
| 43283 | Lap esoph lengthening |
| 43327 | Esoph fundoplasty lap |
| 43328 | Esoph fundoplasty thor |
| 43332 | Transab esoph hiat hern rpr |
| 43333 | Transab esoph hiat hern rpr |
| 43334 | Transthor diaphrag hern rpr |
| 43335 | Transthor diaphrag hern rpr |
| 43336 | Thorabd diaphr hern repair |
| 43337 | Thorabd diaphr hern repair |
| 43338 | Esoph lengthening |
| 47563 | Laparo cholecystectomy/graph |
| 49507 | Prp i/hern init block >5 yr |
| 49521 | Rerepair ing hernia blocked |

| CPT Code | Short Descriptor |
|---|---|
| 49587 | Rpr umbil hern block > 5 yr |
| 49652 | Lap vent/abd hernia repair |
| 49653 | Lap vent/abd hern proc comp |
| 49654 | Lap inc hernia repair |
| 49655 | Lap inc hern repair comp |
| 53445* | Insert uro/ves nck sphincter |
| 60220 | Partial removal of thyroid |
| 60240 | Removal of thyroid |
| 60500 | Explore parathyroid glands |
| 95800 | Slp stdy unattended |
| *CPT code 53445 is currently interim and open for public comment. We are accepting as public comment the nomination information submitted and will address these comments in the CY 2013 PFS final rule with comment period. | |

b. Potentially Misvalued Code Lists

As mentioned above, in the last several annual PFS proposed rules we have identified lists of potentially misvalued codes for review. We believe it is imperative that we continue to identify new lists of potentially misvalued codes for review to appropriately identify, review, and adjust values for potentially misvalued codes for CY 2013.

(1) Review of Harvard-Valued Services with Medicare Allowed Charges of $10,000,000 or More

For many years, we have been reviewing 'Harvard-valued' CPT codes through the potentially misvalued code initiative. The RVUs for Harvard-valued CPT codes have not been reviewed since they were originally valued in the early 1990s at the beginning of the PFS. While the principles underlying the relative value scale have not changed, over time the methodologies we use for valuing services on the PFS have changed, potentially disrupting the relativity between the remaining Harvard-valued codes and other codes on the PFS. At this time, nearly all CPT codes that were Harvard-valued and had Medicare utilization of over 30,000 allowed

services per year have been reviewed. Moving forward, we propose to review Harvard-valued services with Medicare allowed charges of $10 million or greater per year. The CPT codes meeting these criteria have relatively low Medicare utilization (as we have reviewed the services with utilization over 30,000), but account for significant Medicare spending annually and have never been reviewed. We recognize that several of the CPT codes meeting these criteria have already been identified as potentially misvalued through other screens and may currently be scheduled for review for CY 2013. We also recognize that other codes meeting these criteria have been referred by the AMA RUC to the CPT Editorial Panel. In these cases, we are not proposing re-review of these already identified services, but for the sake of completeness, we include them as a part of this category of potentially misvalued services. We recognize that the relatively low Medicare utilization for these services may make gathering information on the appropriate physician work and direct PE inputs difficult. We request recommendations from the AMA RUC and other public commenters, and appreciate efforts expended to provide RVU and input recommendations to CMS for these lower volume services. Because survey sample sizes could be small for these lower volume services, we encourage the use of valid and reliable alternative data sources and methodologies when developing recommended values. In sum, we propose to review Harvard-valued CPT codes with annual allowed charges of $10 million or more as a part of the potentially misvalued codes initiative. Table 7 lists the codes that meet these criteria using CY 2011 Medicare claims data.

**TABLE 7: Harvard-valued CPT Codes with Annual Allowed Charges ≥$10,000,000**

| CPT Code | Short Descriptor |
|---|---|
| 13152* | Repair of wound or lesion |
| 27446 | Revision of knee joint |
| 29823 | Shoulder arthroscopy/surgery |
| 36215** | Place catheter in artery |
| 36245** | Ins cath abd/l-ext art 1st |
| 43264** | Endo cholangiopancreatograph |
| 50360 | Transplantation of kidney |
| 52353* | Cystouretero w/lithotripsy |
| 64450* | N block other peripheral |
| 64590 | Insrt/redo pn/gastr stimul |
| 66180 | Implant eye shunt |
| 67036 | Removal of inner eye fluid |
| 67917 | Repair eyelid defect |
| 92286** | Internal eye photography |
| 92982* | Coronary artery dilation |
| 95860* | Muscle test one limb |
| *Scheduled for CY 2012 AMA RUC Review | |
| **Referred by the AMA RUC to the CPT Editorial Panel | |

(2) Review of Services with Stand Alone PE Procedure Time

Improving the accuracy of procedure time assumptions used in PFS ratesetting continues to be a high priority of the potentially misvalued codes initiative. Procedure time is a critical measure of the resources typically used in furnishing particular services to Medicare beneficiaries, and procedure time assumptions are an important component in the development of work and PE RVUs. Discussions in the academic community have indicated that procedure times used for PFS ratesetting are overstated (McCall, N., J. Cromwell, et al. (2006). "Validation of physician survey estimates of surgical time using operating room logs." Med Care Res Rev 63(6): 764-777. Cromwell, J., S. Hoover, et al. (2006). "Validating CPT typical times for Medicare office evaluation and management (E/M) services." Med Care Res Rev 63(2): 236-255. Cromwell, J., N. McCall, et al. (2010). "Missing productivity gains in the Medicare

physician fee schedule: where are they?" Med Care Res Rev 67(6): 236-255.) MedPAC and others have emphasized the importance of using the best available procedure time information in establishing accurate PFS payment rates. (MedPAC, Report to the Congress: Aligning Incentives in Medicare, June 2010, p. 230)

In recent years, CMS and the AMA RUC have taken steps to consider the accuracy of available data regarding procedure times used in the valuation of the physician work component of PFS payment. Generally, the AMA RUC derives estimates of physician work time from survey responses, and the AMA RUC reviews and analyzes those responses as part of its process for developing a recommendation for physician work. These procedure time assumptions are also used in determining the appropriate direct PE input values used in developing nonfacility PE RVUs. Specifically, physician intra-service time serves as the basis for allocating the appropriate number of minutes within the service period to account for the time used in furnishing the service to the patient. The number of intra-service minutes, or occasionally a particular proportion thereof, is allocated to both the clinical staff that assists the physician in furnishing the service and to the equipment used by either the physician or the staff in furnishing the service. This allocation reflects only the time the beneficiary receives treatment and does not include resources used immediately prior to or following the service. Additional minutes are often allocated to both clinical labor and equipment resources in order to account for the time used for necessary preparatory tasks immediately preceding the procedure or tasks typically performed immediately following it. For codes without physician work, the procedure times assigned to the direct PE inputs for such codes assume that the clinical labor performs the procedure. For these codes, the number of intra-service minutes assigned to clinical staff is independent and not based on any physician intra-service time assumptions. Consequently, the

procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by the AMA RUC and physician community in providing recommendations to CMS, and by CMS in the valuation of the physician work component of PFS payment. These independent clinical labor time assumptions largely determine the RVUs for the procedure. To ensure that procedure time assumptions are as accurate as possible across the Medicare PFS, we believe that codes without physician work should be examined with the same degree of scrutiny as services with physician work.

For CY 2012, a series of radiation treatment services were reviewed as part of the potentially misvalued code initiative. Among these were intensity modulated radiation therapy (IMRT) delivery services and stereotactic body radiation therapy (SBRT) delivery services reported with CPT codes 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) 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), respectively. CPT code 77418 (IMRT treatment delivery) had been identified as potentially misvalued based on Medicare utilization data that indicated both fast growth in utilization and frequent billing with other codes. We identified this code as potentially misvalued in the CY 2009 PFS proposed rule (73 FR 38586). CPT code 77373 (SBRT treatment delivery) had been identified as potentially misvalued by the RUC as a recently established code describing services that use new technologies. There is no physician work associated with either of these codes since other codes are used to bill for planning, dosimetry, and radiation guidance. Both codes are billed per treatment session. Because the physician work associated with these treatments is reported using codes distinct from the treatment delivery, the primary determinant of PE RVUs

for these codes is the number of minutes allocated for the procedure time to both the clinical labor (radiation therapist) and the resource-intensive capital equipment included as direct PE inputs.

In the CY 2012 PFS final rule with comment period, we received and accepted without refinement PE recommendations from the AMA RUC for these two codes. (We received the recommendation for CPT code 77418 (IMRT treatment delivery) too late in 2010 to be evaluated for CY 2011 and it was therefore included in the CY 2012 rulemaking cycle.) The AMA RUC recommended minor revisions to the direct PE inputs for the code to eliminate duplicative clinical labor, supplies, and equipment to account for the frequency with which the code was billed with other codes. For CPT code 77373 (SBRT treatment delivery), the RUC recommended no significant changes to the direct PE inputs.

Subsequent to the publication of the final rule, the AMA RUC and other stakeholders informed CMS that the direct PE input recommendation forwarded to CMS for IMRT treatment delivery (CPT code 77418) inadvertently omitted seven equipment items typically used in furnishing the service. These items had been used as direct PE inputs for the code prior to CY 2012. There is broad agreement among stakeholders that these seven equipment items are typically used in furnishing the services described by CPT code 77418. We were unable to reincorporate the items for CY 2012. These omitted items are listed in Table 8. In consideration of the comments from the AMA RUC and other stakeholders, we are proposing to include the seven equipment items omitted from the RUC recommendation for CPT code 77418. These proposed adjustments are also reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We note that the proposed PE RVUs included in

Addendum B to this proposed rule reflect the RVUs that result from application of these proposals.

**TABLE 8: Equipment Inputs Omitted From RUC Recommendation for CPT Code 77418 (IMRT Treatment Delivery)**

| Equipment Code | Equipment Description |
|---|---|
| ED011 | computer system, record and verify |
| ED035 | video camera |
| ED036 | video printer, color (Sony medical grade) |
| EQ139 | intercom (incl. master, pt substation, power, wiring) |
| ER006 | IMRT physics tools |
| ER038 | isocentric beam alignment device |
| ER040 | laser, diode, for patient positioning (Probe) |

It has come to our attention that there are wide discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these services and the procedure times made widely available to Medicare beneficiaries and the general public. Specifically, the direct PE inputs for IMRT treatment delivery (CPT code 77418) reflect a procedure time assumption of 60 minutes. These procedure minutes were first assigned to the code for CY 2002 based on a recommendation from the AMA RUC indicating that the typical treatment time for the IMRT patient was 40 to 70 minutes. The most recent RUC recommendation that CMS received for CY 2012 rulemaking supported the procedure time assumption of 60 minutes.

Information publicly available to Medicare beneficiaries and the general public clearly indicates that IMRT sessions typically last between 10 and 30 minutes. For example, the American Society for Radiation Oncology (ASTRO) publishes a patient fact sheet that explains that for all external beam radiation therapy, including IMRT, "treatment is delivered in a series of daily sessions, each about 15 minutes long." ["Radiation Therapy for Prostate Cancer: Facts

to Help Patients Make an Informed Decision" available for purchase at www.astro.org/MyASTRO/Products/Product.aspx?AstroID=6901.] This fact sheet is intended for patients with prostate cancer, the typical diagnosis for Medicare beneficiaries receiving IMRT. Similarly, the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) co-sponsor a website for patients called http://radiologyinfo.org that states that IMRT "treatment sessions usually take between 10 and 30 minutes."

The direct PE inputs for SBRT treatment delivery (CPT code 77373) reflect a procedure time assumption of 90 minutes. These procedure minutes were first assigned to the code for CY 2007 based on a recommendation from the AMA RUC. The most recent RUC recommendation that CMS received for CY 2012 rulemaking supported continuing that procedure time assumption.

In 2012, information publicly available to Medicare beneficiaries and the general public states that SBRT treatment typically lasts no longer than 60 minutes. For example, the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) website, http://radiologyinfo.org, states that SBRT "treatment can take up to one hour."

Given the importance of the procedure time assumption in the development of RVUs for these services, using the best available information is critical to ensuring that these services are valued appropriately. We have no reason to believe that information medical societies and practitioners offer to their cancer patients regarding the IMRT or SBRT treatment experience is inaccurate or atypical. Therefore, we believe that the typical procedure time for IMRT delivery is between 10 and 30 minutes and that the typical procedure time for SBRT delivery is under 60 minutes. The services are currently valued using procedure time assumptions of 60 and 90 minutes, respectively. We believe these procedure time assumptions, distinct from necessary

preparatory or follow-up tasks by the clinical labor, are clearly outdated and need to be updated using the best information available.

While we generally have not used publicly available resources to establish procedure time assumptions, we believe that the procedure time assumptions used in setting payment rates for the Medicare PFS should be derived from the most accurate information available. In the case of these services, we believe that the need to reconcile the vast discrepancies between our existing assumptions and more accurate information outweighs the potential value in maintaining relativity offered by only considering data from one source. We are proposing to adjust the procedure time assumption for IMRT delivery (CPT code 77418) to 30 minutes. We are proposing to adjust the procedure time assumption for SBRT delivery (CPT code 77373) to 60 minutes. These procedure time assumptions reflect the maximum number of minutes reported as typical in publicly available information. We note that in the case of CPT code 77418, the 'accelerator, 6-18 MV' (ER010) and the 'collimator, multileaf system w-autocrane' (ER017) are used throughout the procedure and currently have no minutes allocated for preparing the equipment, positioning the patient, or cleaning the room. Since these clinical labor tasks are associated with related codes typically reported at the same time, we are also proposing to allocate minutes to these equipment items to account for their use immediately before and following the procedure. All of these proposed adjustments are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We also note that the proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from the application of this proposal. We request recommendations from the AMA RUC and other public commenters on the direct PE inputs for these services

While we recognize that using these procedure time assumptions will result in payment reductions for these particular services, we believe such changes are necessary to appropriately value these services. Recent attention from popular media sources like the Wall Street Journal (online.wsj.com/article/SB10001424052748703904804575631222900534954.html December 7,2010 ) and the *Washington Post* (www.washingtonpost.com/wp-dyn/content/article/2011/02/28/AR2011022805378.html) February 28, 2011 has encouraged us to consider the possibility that potential overuse of IMRT services may be partially attributable to financial incentives resulting from inappropriate payment rates. In its 2010 Report to Congress, MedPAC referenced concerns that financial incentives may influence how cancer patients are treated. In the context of the growth of ancillary services in physicians' offices, MedPAC recommended that improving payment accuracy for discrete services should be a primary tool used by CMS to mitigate incentives to increase volume (Report to Congress: Aligning Incentives in Medicare, June 2010, p. 225). We note that in recent years, PFS nonfacility payment rates for IMRT treatment delivery have exceeded the Medicare payment rate for the same service paid through the hospital Outpatient Prospective Payment System (OPPS). We believe that such high-volume services that are widely furnished in both nonfacility and facility settings are highly unlikely to be more resource-intensive in freestanding radiation therapy centers or physicians' offices than when furnished in facilities like hospitals that generally incur higher overhead costs, maintain a 24 hour, 7 day per week capacity, are generally paid in larger bundles, and generally furnish services to higher acuity patients than the patients who receive services in physician offices or free-standing clinics. Given that the OPPS payment rates are based on auditable data on hospital costs, we believe the seemingly counterintuitive relationship between the OPPS and nonfacility PFS payment rates reflects inappropriate

assumptions within the current direct PE inputs for CPT code 77418. The AMA RUC's most recent direct PE input recommendations reflect the same procedure time assumptions used in developing the recommendations for CY 2002. As we explained above, we do not understand how the AMA RUC can recommend these assumptions in the context of the procedure time information available to the general public. We believe that using procedure time assumptions that reflect the maximum times reported as typical to Medicare beneficiaries will improve the accuracy of those inputs and the resulting nonfacility payment rates.

These two treatment delivery codes are PE only codes and are fairly unique in that the resulting RVUs are largely comprised of resources for staff and equipment based on the minutes associated with clinical labor. There are several other codes on the PFS established through the same methodology. As we previously stated, we believe that the procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by CMS in the valuation of the physician work component of PFS payment. In light of observations about publicly available procedure times for CPT codes 77418 (IMRT treatment delivery) and 77373 (SBRT treatment delivery) and public awareness of potential adverse financial incentives associated with IMRT treatment delivery in particular, we believe that similar codes are potentially misvalued.

Therefore, consistent with the requirement in section 1848(c)(2)(K)(ii) of the Act to examine other codes determined to be appropriate by the Secretary, we are proposing to review and make adjustments to CPT codes with stand alone procedure time assumptions used in developing nonfacility PE RVUs. These procedure time assumptions are not based on physician time assumptions. We are prioritizing for review CPT codes that have annual Medicare allowed charges of $100,000 or more, include direct equipment inputs that amount to $100 or more, and

have PE procedure times of greater than 5 minutes. At this time, we are not including in this category services with payment rates subject to the OPPS cap (as specified in the statute under section 1848(b)(4) of the Act and listed in Addendum G to this proposed rule) or services with PE minutes established through code descriptors. (For example, an overnight monitoring code might contain 480 minutes of monitoring equipment time to account for 8 hours of overnight monitoring.) The CPT codes meeting these criteria appear in Table 9. We recognize that there are other CPT codes that are valued in the same manner. We may consider evaluating those services as potentially misvalued codes in future rulemaking.

For the services in Table 9, we request recommendations from the AMA RUC and other public commenters on the appropriate direct PE inputs for these services. We encourage the use of valid and reliable alternative data sources when developing recommended values, including electronic medical records and other independent data sources. We note that many of the CPT codes in Table 9 have been identified through other potentially misvalued code screens and have been recently reviewed. Given our observed concerns with the inputs for the recently reviewed IMRT and SBRT direct PE inputs discussed above, we believe it is necessary to re-review other recently reviewed services with stand alone PE procedure time.

**TABLE 9: Services with Stand Alone PE Procedure Time**

| CPT Code | Short Descriptor |
|---|---|
| 77280 | Set radiation therapy field |
| 77285 | Set radiation therapy field |
| 77290 | Set radiation therapy field |
| 77301 | Radiotherapy dose plan imrt |
| 77338 | Design mlc device for imrt |
| 77372 | Srs linear based |
| 77373 | Sbrt delivery |
| 77402 | Radiation treatment delivery |
| 77403 | Radiation treatment delivery |
| 77404 | Radiation treatment delivery |

| CPT Code | Short Descriptor |
|---|---|
| 77406 | Radiation treatment delivery |
| 77407 | Radiation treatment delivery |
| 77408 | Radiation treatment delivery |
| 77409 | Radiation treatment delivery |
| 77412 | Radiation treatment delivery |
| 77413 | Radiation treatment delivery |
| 77414 | Radiation treatment delivery |
| 77416 | Radiation treatment delivery |
| 77418 | Radiation tx delivery imrt |
| 77600 | Hyperthermia treatment |
| 77785 | Hdr brachytx 1 channel |
| 77786 | Hdr brachytx 2-12 channel |
| 77787 | Hdr brachytx over 12 chan |
| 88348 | Electron microscopy |

c. Services with Anomalous Time

Each year when we publish the PFS proposed and final rules, we publish on the CMS Website several files that support annual PFS rate-setting. One of these supporting files is the physician time file, which lists the physician time associated with the HCPCS codes on the PFS. The physician time file associated with this PFS proposed rule is available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

In our review of potentially misvalued codes and their inputs, we became aware of several HCPCS codes that have anomalous times in our physician time file. Physician work is a measure of physician time and intensity, so there should be no services that have payable physician work RVUs but no physician time in the time file, and there should be no payable services with physician time in the time file and no physician work RVUs. For CY 2013 we are proposing to make the physician time file changes detailed below to address these anomalous time file entries.

(1) Review of Services with Physician Work and No Listed Physician Time

CPT code 94014 (Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and physician review and interpretation) has a physician work RVU of 0.52 and is currently listed with 0 physician time. CPT code 94014 is a global service that includes CPT code 94015 (Patient-initiated spirometric recording per 30-day period of time; recording (includes hook-up, reinforced education, data transmission, data capture, trend analysis, and periodic recalibration)) (the technical component), and CPT code 94016 (Patient-initiated spirometric recording per 30-day period of time; physician review and interpretation only) (the professional component). We believe it is appropriate for the physician time of CPT code 94014 to match the physician time of the code's component professional service—CPT code 94016. As such, for CPT code 94014 for CY 2013, we are proposing to assign 2 minutes of pre-service evaluation time, and 20 minutes of intra-service time, which matches the times associated with CPT code 94016. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

HCPCS codes G0117 (Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist) and G0118 (Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist) both have physician work RVUs (0.45, and 0.17, respectively), but neither code is included in the physician time file. HCPCS codes G0117 and G0118 have a PFS procedure status indicator of T indicating that these services are only paid if there are no other services payable under the PFS billed on the same date by the same provider.

In the CY 2002 PFS final rule (66 FR 55274), we crosswalked the physician work of HCPCS code G0117 from CPT code 99212 (Level 2 office or other outpatient visit, established patient), and we crosswalked the physician work of HCPCS code G0118 from CPT code 99211 (Level 1 office or other outpatient visit, established patient). Based on these finalized physician work crosswalks, we propose to assign HCPCS code G0117 physician times matching CPT code 99212, and HCPCS code G0118 physician times matching CPT code 99211. Specifically, we are proposing 2 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of immediate post-service time for HCPCS code G0117, and 5 minutes of intra-service time, and 2 minutes of immediate post-service time for HCPCS code G0118. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

HCPCS code G0128 (Direct (face-to-face with patient) skilled nursing services of a registered nurse provided in a comprehensive outpatient rehabilitation facility, each 10 minutes beyond the first 5 minutes) currently has a physician work RVU ( 0.08), but is not listed in the physician time file. After review of this HCPCS code, we do not believe that HCPCS code G0128 describes a service that includes physician work. Time for a registered nurse to furnish the service is included in the PE for the code. As such, for CY 2013, we propose to remove the physician work RVU for HCPCS code G0128. HCPCS code G0128 will continue to have PE and malpractice expense RVUs.

HCPCS codes G0245 (Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) the diagnosis of LOPS; (2) a patient history; (3) a physical examination that consists

of at least the following elements: (a) visual inspection of the forefoot, hindfoot and toe web spaces; (b) evaluation of a protective sensation; (c) evaluation of foot structure and biomechanics; (d) evaluation of vascular status and skin integrity; and (e) evaluation and recommendation of footwear; and (4) patient education), G0246 (Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) a patient history; (2) a physical examination that includes: (a) visual inspection of the forefoot, hindfoot and toe web spaces; (b) evaluation of protective sensation; (c) evaluation of foot structure and biomechanics; (d) evaluation of vascular status and skin integrity; and (e) evaluation and recommendation of footwear; and (3) patient education), and G0247 (Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include, the local care of superficial wounds (that is, superficial to muscle and fascia) and at least the following if present: (1) local care of superficial wounds; (2) debridement of corns and calluses; and (3) trimming and debridement of nails) have physician work RVUs of 0.88, 0.45, and 0.50, respectively, but are not listed in the physician time file. HCPCS codes G0245, G0246, and G0247 have a procedure status indicator of R on the PFS indicating that coverage of these services is restricted.

In the CY 2003 PFS final rule (67 FR 79990), we crosswalked the physician work of HCPCS code G0245 from CPT code 99202 (Level 2 office or other outpatient visits, new patient), we crosswalked the physician work of HCPCS code G0246 from CPT code 99212, and we crosswalked the physician work of HCPCS code G0257 from CPT code 11040 (Debridement; skin; partial thickness). Based on these finalized physician work crosswalks, we propose to assign HCPCS code G0245 physician times matching CPT code 99202, HCPCS code

G0246 physician times matching CPT code 99212, and HCPCS code G0247 physician times matching CPT code 11040. Specifically, for HCPCS code G0245 we are proposing 2 minutes of pre-service time, 15 minutes of intra-service time, and 5 minutes of immediate post-service time. For HCPCS code G0246 we are proposing 2 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of immediate post-service time. For HCPCS code G0247 we are proposing 7 minutes of pre-service time, 10 minutes of intra-service time, and 7 minutes of immediate post-service time. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

HCPCS code G0250 (Physician review, interpretation, and patient management of home INR (International Normalized Ratio) testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests) has a physician work RVU of 0.18 but is not listed in the physician time file. HCPCS code G0250 has a procedure status indicator of R on the PFS indicating that coverage of this service is restricted. In the CY 2003 final rule (67 FR 79991), we assigned HCPCS code G0250 a work RVU of 0.18, which corresponds to the work RVU of CPT code 99211. While we did not articulate this as a direct crosswalk in the CY 2003 final rule, after clinical review we believe that HCPCS code G0250 continues to require similar work as CPT code 99211, and should have the same amount of physician time as CPT code 99211. As such, we are proposing to assign HCPCS code G0250 the same physician time as CPT code 99211. Specifically, for HCPCS code G0250 we are proposing 5 minutes of intra-service time and 2 minutes of immediate post-service time. These proposed adjustments are reflected in the physician time file associated with this

proposed rule, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

During our annual review of new, revised, and potentially misvalued CPT codes, the assessment of physician time used to furnish a service is an important part of the clinical review when determining the appropriate work RVU for a service. However, the time in the physician time file is not used to automatically adjust the physician work RVUs outside of that clinical review process. As such, the proposed addition of physician time to the HCPCS codes discussed above will have no impact on the current physician work RVUs for these services.

The time data in the physician time file is used in the PE methodology described in section II.A.2. In creating the indirect practice cost index (IPCI), we 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. The proposed addition of physician time to the HCPCS codes discussed above will affect the aggregate pools of indirect PE at the specialty level. However because the services discussed above have low utilization and low total time, the impact of the physician time changes on the IPCI is negligible, and likely would have a modest impact if any on the PE RVUs at the individual code level.

(2) Review of Services with Stand Alone PE Procedure Time

There are a number of services that have no physician work RVUs, yet include physician time in the physician time file. Many of these services are not payable under the PFS or are contractor priced services where the physician time is not used to nationally price the services on the PFS. We are not proposing to remove the physician time from the time file for these services as the time has no effect on the calculation of RVUs for the PFS. However, there are several

CPT codes, listed in Table 10, that are payable under the PFS and have no physician work RVUs yet include time in the physician time file. We are proposing to remove the physician time from the time file for these seven CPT codes. These proposed adjustments are reflected in the physician time file associated with this proposed rule, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

**TABLE 10: Payable CPT Codes with Physician Time and No Physician Work**

| CPT Code | Short Descriptor | PFS Procedure Status | CY 2012 Total Physician Time |
|---|---|---|---|
| 22841 | Insert spine fixation device | B (Bundled, not separately payable) | 5 minutes |
| 51798 | Us urine capacity measure | A (Active, payable) | 9 minutes |
| 95990 | Spin/brain pump refill & main | A (Active, payable) | 40 minutes |
| 96904 | Whole body photography | R (Restricted coverage) | 80 minutes |
| 96913 | Photochemotherapy uv-a or b | A (Active, payable) | 90 minutes |
| 97545 | Work hardening | R(Restricted coverage) | 120 minutes |
| 97602 | Wound(s) care non-selective | B (Bundled, not separately payable) | 36 minutes |

As mentioned above and as discussed in section II.A.2. of this proposed rule, to create the IPCI used in the PE methodology, we 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 performed by the specialty. The proposed removal of physician time from the CPT codes discussed above will affect the aggregate pools of indirect PE at the specialty level. However because the services discussed above have low utilization and/or low total time, the impact of the physician time changes on the IPCI is negligible, and likely would have a modest impact if any on the PE RVUs at the individual code level.

4. Expanding 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 the service for certain sets of services 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 practice expense (PE) or professional work or both when services are furnished together. With the exception of a few codes that are always reported along with another code, the Medicare PFS values services independently to recognize relative resources involved when the service is the only one furnished in a session. While our general policy for MPPRs precedes the Affordable Care Act, this payment policy approach addresses the fourth category of potentially misvalued codes identified in section 1848(c)(2)(K) of the Act, as added by section 3134(a) of the Affordable Care Act, which is "multiple codes that are frequently billed in conjunction with furnishing a single service" (see 75 FR 73216).

For CY 2013, we are proposing to continue our work to recognize resource efficiencies when certain services are furnished together. We are proposing to apply an MPPR to the technical component (TC) of certain diagnostic tests. As discussed in the CY 2012 final rule with comment period (76 FR 73079), we are also proceeding with applying the current MPPR policy for imaging services to services furnished in the same session by physicians in the same group practice.

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient 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 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, not across families. Additionally, the MPPR policy originally applied to TC-only services and to the TC of global services, and 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, the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) 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 the new OPPS payment cap added by the DRA, we decided in the PFS final rule with comment period for 2006 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 BN provision. Effective July 1, 2010, section 1848(b)(4)(C) of the Act, as added by section 3135(b)(1) of the Affordable Care 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, as added by section 3135(b)(2) of the Affordable Care Act exempted the reduced expenditures attributable to this further change from the PFS BN 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 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 CYs 2009 and 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 patient 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), while 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 BN adjustment, it does not apply to reduced expenditures attributable to our policy change regarding additional code combinations across code families (non-continguous body areas) that are subject to BN 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, and add-on codes. The complete list of codes subject to the MPPR policy for therapy services is included in Addendum H.

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 patient 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 patient 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 (which are services furnished in office settings, or non-institutional services). The payment reduction percentage remains 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 BN provision. Under our current policy as amended by the PPTRA, for institutional services, 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 25 percent. For non-institutional services, 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 20 percent.

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 patient on the same day. It applies to services furnished by an individual or group practice or "incident to" a physician's service. The MPPR applies when multiple therapy services are billed on the same date of service for one patient 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 patients 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, 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 (see Addendum F). 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 patient 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 procedure, and payment is reduced by 25 percent for the PC for each additional procedure furnished to the same patient 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, with smaller 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 both with our longstanding policy 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 2012 proposed rule (76 FR 42812), we also invited public comment on the following MPPR policies under consideration. We noted that any proposals would be presented in future rulemaking and subject to further public comment:

- Apply the MPPR to the TC of All Imaging Services. This approach would apply a payment reduction to the TC of the second and subsequent imaging services furnished in the same session. Such an approach could define imaging consistent with our existing definition of imaging for purposes of the statutory cap on PFS payment at the OPPS rate (including x-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography). Add-on codes that are always furnished

with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time when multiple services are furnished together. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

- Apply the MPPR to the PC of All Imaging Services. This approach would apply a payment reduction to the PC of the second or subsequent imaging services furnished in the same encounter. Such an approach could define imaging consistent with our existing definition of imaging for the cap on payment at the OPPS rate. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on efficiencies due to duplication of physician work primarily in the pre- and post-service periods, with smaller efficiencies in the intraservice period, when multiple services are furnished together. This approach would apply to approximately 530 HCPCS codes, including the 119 codes to which the current imaging MPPR applies. Savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

- Apply the MPPR to the TC of All Diagnostic Tests. This approach would apply a payment reduction to the TC of the second and subsequent diagnostic tests (such as radiology, cardiology, audiology, etc.) furnished in the same encounter. Add-on codes that are always furnished with another service and have been valued accordingly could be excluded.

Such an approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time when multiple services are furnished together. The approach would apply to approximately 700 HCPCS codes, including the

approximately 560 HCPCS codes that are currently subject to the OPPS cap. The savings would be redistributed to other PFS services as required by the statutory PFS BN provision.

b. MPPR Policy Clarifications

(1) Apply the MPPR to Two Nuclear Medicine Procedures

As indicated previously, effective January 1, 1995, we implemented an MPPR for six nuclear medicine codes. Under the current policy, full payment is made for the highest paid procedure, and payment is reduced by 50 percent for the second procedure furnished to the same patient on the same day. Due to a technical error, the MPPR is not being applied to CPT codes 78306 (Bone imaging; whole body when followed by CPT code 78320 (Bone imaging; SPECT). We will apply the MPPR to these procedures effective January 1, 2013.

(2) Apply the MPPR to the PC and TC of Advanced Imaging Procedures to Physicians in the Same Group Practice

As indicated in the CY 2012 final rule (76 FR 73077-73079), we finalized a policy to apply the MPPR to the PC and TC of the second and subsequent advanced imaging procedures furnished to the same patient in the same session by a single physician or by multiple physicians in the same group practice. Due to operational limitations, we were not able to apply this MPPR to multiple physicians in the same group practice during CY 2012. In addition, after we issued the CY 2012 final rule with comment period, some stakeholders asserted that they had not commented on the application of the MPPR to physicians in the same group practice because that policy was not explicit in the CY 2012 proposed rule discussion expanding the MPPR for advanced imaging to the PC. We have resolved the operational problems and, therefore, for services furnished on or after January 1, 2013 we will apply the MPPR to both the PC and the TC of advanced imaging procedures to multiple physicians in the same group practice (same

group NPI). Under this policy, the MPPR will apply when one or more physicians in the same group practice furnish services to the same patient, in the same session, on the same day. This policy is consistent with other PFS MPPR policies for surgical and therapy procedures. We continue to believe that the typical efficiencies achieved when the same physician is furnishing multiple procedures also accrue when different physicians in the same group furnish multiple procedures involving the same patient in the same session. It is our general intention to apply this and future MPPRs to services furnished by one or more physicians in the same group unless special circumstances warrant a more limited application. In such circumstances, we will note in our proposal that an MPPR does not apply to one or more physicians in the same group as other MPPR policies do. We continue to welcome public comment on this provision as it applies to advanced diagnostic imaging and to the MPPR policy generally.

c. Proposed MPPR for the TC of Cardiovascular and Ophthalmology Services.

As noted above, we continue to examine whether it would be appropriate to apply MPPR policies to other categories of services that are frequently billed together, including the TC for other diagnostic services. For CY 2013, we examined other diagnostic services to determine whether there typically are efficiencies in the technical component when multiple diagnostic services are furnished together on the same day. We have conducted an analysis of the most frequently furnished code combinations for all diagnostic services using CY 2011 claims data. Of the several areas of diagnostic tests that we examined, we found that billing patterns and PE inputs indicated that cardiovascular and ophthalmology diagnostic procedures, respectively, are frequently furnished together and that there is some duplication in PE inputs when this occurs. For cardiovascular diagnostic services, we reviewed the code pair/combinations with the highest utilization in code ranges 75600 through 75893, 78414 through 78496, and 93000 through

93990. For ophthalmology diagnostic services, we reviewed the code pair/combinations with the highest utilization in code ranges 76510 through 76529 and 92002 through 92371. The most frequently billed cardiovascular and ophthalmology diagnostic code combinations are listed in Tables 14 and 15.

Under the resource-based PE methodology, specific PE inputs of clinical labor, supplies, and equipment are used to calculate PE RVUs for each individual service. When multiple diagnostic tests are furnished to the same patient on the same day, most of the clinical labor activities and some supplies are not furnished twice. We have identified the following clinical labor activities that typically would not be duplicated for subsequent procedures:

- Greeting and gowning the patient.
- Preparing the room, equipment and supplies.
- Education and consent.
- Completing diagnostic forms.
- Preparing charts.
- Taking history.
- Taking vitals.
- Preparing and positioning the patient.
- Cleaning the room.
- Monitoring the patient.
- Downloading, filing, identifying and storing photos
- Developing film.
- Collating data.
- QA documentation.

- Making phone calls.
- Reviewing prior X-rays, lab and echos.

We analyzed the CY 2011 claims data for the most frequently billed cardiovascular and ophthalmology diagnostic code combinations in order to determine the level of duplication present when multiple services are furnished to the same patient on the same day. Our MPPR determination excludes the clinical staff minutes associated with the activities that are not duplicated for subsequent procedures. For purposes of this analysis, we retained the higher number of minutes for each duplicated clinical activity, regardless of the code in the pair with which those clinical labor minutes were associated. Equipment time and indirect costs are allocated based on clinical labor time; therefore, these inputs were reduced accordingly. While we observed that some supplies are duplicated, we did not factor these into our calculations because they were low cost and had little impact on our estimate of the level of duplication for each code pair.

When we removed the PE inputs for activities that are not duplicated, and adjusted the equipment time and indirect costs, we found support for payment reductions ranging from 8 to 57 percent for second and subsequent cardiovascular procedures (volume-adjusted average reduction across all code pairs of 25 percent); and payment reductions ranging from 9 to 62 percent for second and subsequent ophthalmology procedures (volume-adjusted average reduction across all code pairs of 32 percent). Because we found a relatively wide range of reduction by code pair, we believe that an across-the-board reduction of 25 percent for second and subsequent procedures (which is approximately the average reduction supported by our analysis) would be appropriate. We propose to apply an MPPR to TC-only services and to the TC portion of global services for the procedures listed in Tables 12 and 13. The MPPR would

apply independently to second and subsequent cardiovascular services and to second and subsequent ophthalmology services. We propose to make full payment for the TC of the highest priced procedure and to make payment at 75 percent (that is, a 25 percent reduction) of the TC for each additional procedure furnished by the same physician (or physicians in the same group practice, that is, the same group practice NPI) to the same patient on the same day. We are not proposing to apply an MPPR to the PC for cardiovascular and ophthalmology services at this time. In Table 11, we provide examples illustrating the current and proposed payment amounts:

**TABLE 11: Illustration of Current and Proposed Payments**

| **Sample Cardiovascular Payment Reduction *** | | | | | |
|---|---|---|---|---|---|
| | Code | Code | Total Current | Total Proposed | Payment |
| | 78452 | 93306 | Payment | Payment | Calculation |
| PC | $77.00 | $65.00 | $142.00 | $142.00 | no reduction |
| TC | $427.00 | $148.00 | $575.00 | $538.00 | $427 + (.75 x $148) |
| Global | $504.00 | $213.00 | $717.00 | $680.00 | $142 + $427 + (.75 x $148) |
| **Sample Ophthalmology Payment Reduction *** | | | | | |
| | Code | Code | Total Current | Total Proposed | Payment |
| | 92235 | 92250 | Payment | Payment | Calculation |
| PC | $46.00 | $23.00 | $69.00 | $69.00 | no reduction |
| TC | $92.00 | $53.00 | $145.00 | $131.75 | $92 + (.75 x $53) |
| Global | $138.00 | $76.00 | $214.00 | $200.75 | $69 + $92 + (.75 x $53) |

*Dollar amounts are for illustrative purposes and may not reflect actual payment amounts.

We believe that the proposed MPPR percentage represents an appropriate reduction for the typical delivery of multiple cardiovascular and ophthalmology services on the same day. Because the reduction is based on discounting the specific PE inputs that are not duplicated for second and subsequent services, the proposal is consistent with our longstanding policy on surgical and nuclear medicine diagnostic procedures and advanced imaging procedures which applies a 50 percent reduction to second and subsequent procedures, and our more recent policy

on therapy services, which applies a 20 or 25 percent reduction depending on the setting.

Furthermore, it is consistent with section 1848(c)(2)(K) of the Act which 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.

Finally, it is responsive to continued concerns about significant growth in spending on imaging and other diagnostic services, and to MedPAC (March 2010) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies. Savings resulting from this proposal would be redistributed to other PFS services as required by the general statutory PFS BN provision. In summary, for services furnished on or after January 1, 2013, we plan to apply the MPPR to nuclear medicine procedures to CPT codes 78306 (Bone imaging; whole body when followed by CPT code 78320 (Bone imaging; SPECT). We plan to apply the MPPR to the PC and the TC of advanced imaging procedures to multiple physicians in the same group practice (same group NPI). Therefore, the MPPR will apply when one or more physicians in the same group practice furnish services to the same patient, in the same session, on the same day. Finally, we propose to apply an MPPR to TC-only services and to the TC portion of global services for diagnostic cardiovascular and ophthalmology procedures. The reduction would apply independently to cardiovascular and ophthalmology services. We propose to make full payment for the TC of the highest priced procedure and payment at 75 percent of the TC for each additional procedure furnished by the same physician (or physicians in the same group practice, that is, the same group practice NPI) to the same patient on the same day.

**TABLE 12: Diagnostic Cardiovascular Services Subject to the Multiple Procedure Payment Reduction**

| Code | Descriptor |
|---|---|
| 75600 | Contrast x-ray exam of aorta |
| 75605 | Contrast x-ray exam of aorta |
| 75625 | Contrast x-ray exam of aorta |
| 75630 | X-ray aorta leg arteries |
| 75650 | Artery x-rays head & neck |
| 75658 | Artery x-rays arm |
| 75660 | Artery x-rays head & neck |
| 75662 | Artery x-rays head & neck |
| 75665 | Artery x-rays head & neck |
| 75671 | Artery x-rays head & neck |
| 75676 | Artery x-rays neck |
| 75680 | Artery x-rays neck |
| 75685 | Artery x-rays spine |
| 75705 | Artery x-rays spine |
| 75710 | Artery x-rays arm/leg |
| 75716 | Artery x-rays arms/legs |
| 75726 | Artery x-rays abdomen |
| 75731 | Artery x-rays adrenal gland |
| 75733 | Artery x-rays adrenals |
| 75736 | Artery x-rays pelvis |
| 75741 | Artery x-rays lung |
| 75743 | Artery x-rays lungs |
| 75746 | Artery x-rays lung |
| 75756 | Artery x-rays chest |
| 75774 | Artery x-ray each vessel |
| 75791 | Av dialysis shunt imaging |
| 75809 | Nonvascular shunt x-ray |
| 75820 | Vein x-ray arm/leg |
| 75822 | Vein x-ray arms/legs |
| 75825 | Vein x-ray trunk |
| 75827 | Vein x-ray chest |
| 75831 | Vein x-ray kidney |
| 75833 | Vein x-ray kidneys |
| 75840 | Vein x-ray adrenal gland |
| 75842 | Vein x-ray adrenal glands |
| 75860 | Vein x-ray neck |
| 75870 | Vein x-ray skull |
| 75872 | Vein x-ray skull |
| 75880 | Vein x-ray eye socket |
| 75885 | Vein x-ray liver |
| 75887 | Vein x-ray liver |
| 75889 | Vein x-ray liver |

| Code | Descriptor |
|---|---|
| 75891 | Vein x-ray liver |
| 75893 | Venous sampling by catheter |
| 78428 | Cardiac shunt imaging |
| 78445 | Vascular flow imaging |
| 78451 | Ht muscle image spect sing |
| 78452 | Ht muscle image spect mult |
| 78453 | Ht muscle image planar sing |
| 78454 | Ht musc image planar mult |
| 78456 | Acute venous thrombus image |
| 78457 | Venous thrombosis imaging |
| 78458 | Ven thrombosis images bilat |
| 78466 | Heart infarct image |
| 78468 | Heart infarct image (ef) |
| 78469 | Heart infarct image (3D) |
| 78472 | Gated heart planar single |
| 78473 | Gated heart multiple |
| 78481 | Heart first pass single |
| 78483 | Heart first pass multiple |
| 78494 | Heart image spect |
| 78496 | Heart first pass add-on |
| 93005 | Electrocardiogram tracing |
| 93017 | Cardiovascular stress test |
| 93318 | Echo transesophageal intraop |
| 93024 | Cardiac drug stress test |
| 93025 | Microvolt t-wave assess |
| 93041 | Rhythm ecg tracing |
| 93225 | Ecg monit/reprt up to 48 hrs |
| 93226 | Ecg monit/reprt up to 48 hrs |
| 93229 | Remote 30 day ecg tech supp |
| 93270 | Remote 30 day ecg rev/report |
| 93271 | Ecg/monitoring and analysis |
| 93278 | ECG/signal-averaged |
| 93279 | Pm device progr eval sngl |
| 93280 | Pm device progr eval dual |
| 93281 | Pm device progr eval multi |
| 93282 | Icd device prog eval 1 sngl |
| 93283 | Icd device progr eval dual |
| 93284 | Icd device progr eval mult |
| 93285 | Ilr device eval progr |
| 93286 | Pre-op pm device eval |
| 93287 | Pre-op icd device eval |
| 93288 | Pm device eval in person |

| Code | Descriptor |
|---|---|
| 93289 | Icd device interrogate |
| 93290 | Icm device eval |
| 93291 | Ilr device interrogate |
| 93292 | Wcd device interrogate |
| 93293 | Pm phone r-strip device eval |
| 93296 | Pm/icd remote tech serv |
| 93303 | Echo transthoracic |
| 93304 | Echo transthoracic |
| 93306 | Tte w/doppler complete |
| 93307 | Tte w/o doppler complete |
| 93308 | Tte f-up or lmtd |
| 93312 | Echo transesophageal |
| 93314 | Echo transesophageal |
| 93318 | Echo transesophageal intraop |
| 93320 | Doppler echo exam heart |
| 93321 | Doppler echo exam heart |
| 93325 | Doppler color flow add-on |
| 93350 | Stress tte only |
| 93351 | Stress tte complete |
| 93701 | Bioimpedance cv analysis |
| 93724 | Analyze pacemaker system |
| 93786 | Ambulatory BP recording |
| 93788 | Ambulatory BP analysis |
| 93880 | Extracranial study |

| Code | Descriptor |
|---|---|
| 93882 | Extracranial study |
| 93886 | Intracranial study |
| 93888 | Intracranial study |
| 93890 | Tcd vasoreactivity study |
| 93892 | Tcd emboli detect w/o inj |
| 93893 | Tcd emboli detect w/inj |
| 93922 | Upr/l xtremity art 2 levels |
| 93923 | Upr/lxtr art stdy 3+ lvls |
| 93924 | Lwr xtr vasc stdy bilat |
| 93925 | Lower extremity study |
| 93926 | Lower extremity study |
| 93930 | Upper extremity study |
| 93931 | Upper extremity study |
| 93965 | Extremity study |
| 93970 | Extremity study |
| 93971 | Extremity study |
| 93975 | Vascular study |
| 93976 | Vascular study |
| 93978 | Vascular study |
| 93979 | Vascular study |
| 93980 | Penile vascular study |
| 93981 | Penile vascular study |
| 93990 | Doppler flow testing |

**TABLE 13: Diagnostic Ophthalmology Services Subject to the Multiple Procedure Payment Reduction**

| Code | Descriptor |
|---|---|
| 76510 | Ophth us b & quant a |
| 76511 | Ophth us quant a only |
| 76512 | Ophth us b w/non-quant a |
| 76513 | Echo exam of eye water bath |
| 76514 | Echo exam of eye thickness |
| 76516 | Echo exam of eye |
| 76519 | Echo exam of eye |
| 92025 | Corneal topography |
| 92060 | Special eye evaluation |
| 92081 | Visual field examination(s) |
| 92082 | Visual field examination(s) |
| 92083 | Visual field examination(s) |
| 92132 | Cmptr ophth dx img ant segmt |
| 92133 | Cmptr ophth img optic nerve |

| Code | Descriptor |
|---|---|
| 92134 | Cptr ophth dx img post segmt |
| 92136 | Ophthalmic biometry |
| 92228 | Remote retinal imaging mgmt |
| 92235 | Eye exam with photos |
| 92240 | Icg angiography |
| 92250 | Eye exam with photos |
| 92265 | Eye muscle evaluation |
| 92270 | Electro-oculography |
| 92275 | Electroretinography |
| 92283 | Color vision examination |
| 92284 | Dark adaptation eye exam |
| 92285 | Eye photography |
| 92286 | Internal eye photography |

**TABLE 14: Frequently Billed Diagnostic Cardiovascular Combinations**

**Code Range 75600-75893**

| Code | Descriptor | Code | Descriptor | Code | Descriptor | Code | Descriptor |
|---|---|---|---|---|---|---|---|
| 75710 | Artery x-rays arm/leg | 75791 | Av dialysis shunt imaging | | | | |
| 75625 | Contrast x-ray exam of aorta | 75716 | Artery x-rays arms/legs | | | | |
| 75625 | Contrast x-ray exam of aorta | 75716 | Artery x-rays arms/legs | 75774 | Artery x-ray each vessel | | |
| 75820 | Vein x-ray arm/leg | 75827 | Vein x-ray chest | | | | |
| 75625 | Contrast x-ray exam of aorta | 75710 | Artery x-rays arm/leg | | | | |
| 75791 | Av dialysis shunt imaging | 75827 | Vein x-ray chest | | | | |
| 75658 | Artery x-rays arm | 75791 | Av dialysis shunt imaging | 75820 | Vein x-ray arm/leg | 75827 | Vein x-ray chest |
| 75710 | Artery x-rays arm/leg | 75774 | Artery x-ray each vessel | | | | |
| 75820 | Vein x-ray arm/leg | 93931 | Upper extremity study | | | | |
| 75791 | Av dialysis shunt imaging | 75820 | Vein x-ray arm/leg | | | | |

**Code Range 78414-78496**

| Code | Descriptor | Code | Descriptor | Code | Descriptor | Code | Descriptor |
|---|---|---|---|---|---|---|---|
| 78452 | Ht muscle image spect mult | 93306 | Tte w/doppler complete | | | | |
| 78452 | Ht muscle image spect mult | 93017 | Cardiovascular stress test | | | | |
| 78452 | Ht muscle image spect mult | 93306 | Tte w/doppler complete | 93880 | Extracranial study | | |
| 78452TC | Ht muscle image spect mult | 93017 | Cardiovascular stress test | | | | |
| 78452 | Ht muscle image spect mult | 93880 | Extracranial study | | | | |
| 78452TC | Ht muscle image spect mult | 93306 | Tte w/doppler complete | | | | |
| 78452 | Ht muscle image spect mult | 93017 | Cardiovascular stress test | 93306 | Tte w/doppler complete | | |
| 78451 | Ht muscle image spect sing | 93306 | Tte w/doppler complete | | | | |
| 78452TC | Ht muscle image spect mult | 93306TC | Tte w/doppler complete | | | | |
| 78452 | Ht muscle image spect mult | 93306 | Tte w/doppler complete | 93880 | Extracranial study | 93978 | Vascular study |

**Code Range 93000-93990**

| Code | Descriptor | Code | Descriptor | Code | Descriptor |
|---|---|---|---|---|---|
| 93306 | Tte w/doppler complete | 93880 | Extracranial study | | |
| 93320 | Doppler echo exam heart | 93325 | Lower extremity study | 93351 | Stress tte complete |
| 93922 | Upr/l xtremity art 2 levels | 93925 | Lower extremity study | | |
| 93923 | Upr/lxtr art stdy 3+ lvls | 93925 | Lower extremity study | | |
| 93306TC | Tte w/doppler complete | 93880TC | Extracranial study | | |

| | | | |
|---|---|---|---|
| 93880 | Extracranial study | 93978 | Vascular study |
| 93284 | Icd device progr eval mult | 93290 | Icm device eval |
| 93922 | Upr/l xtremity art 2 levels | 93926 | Lower extremity study |
| 93965 | Extremity study | 93970 | Extremity study |
| 93925 | Lower extremity study | 93970 | Extremity study |

**TABLE 15: Frequently Billed Diagnostic Ophthalmology Combinations**

| **Code Range 76510-76529** | | | | | |
|---|---|---|---|---|---|
| **Code** | **Descriptor** | **Code** | **Descriptor** | **Code** | **Descriptor** |
| 76514 | Echo exam of eye thickness | 92133 | Cmptr ophth img optic nerve | | |
| 76514 | Echo exam of eye thickness | 92083 | Visual field examination(s) | 92133 | Cmptr ophth img optic nerve |
| 76514 | Echo exam of eye thickness | 92083 | Visual field examination(s) | | |
| 76514 | Echo exam of eye thickness | 92250 | Eye exam with photos | | |
| 76514 | Echo exam of eye thickness | 92083 | Visual field examination(s) | 92250 | Eye exam with photos |
| 76512 | Ophth us b w/non-quant a | 92134 | Cptr ophth dx img post segmt | | |
| 76512 | Ophth us b w/non-quant a | 92250 | Eye exam with photos | | |
| 76514 | Echo exam of eye thickness | 92286 | Internal eye photography | | |
| 76514 | Echo exam of eye thickness | 92134 | Cptr ophth dx img post segmt | | |
| 76512 | Ophth us b w/non-quant a | 92235 | Eye exam with photos | 92250 | Eye exam with photos |
| **Code Range 92002-92371** | | | | | |
| **Code** | **Descriptor** | **Code** | **Descriptor** | **Code** | **Descriptor** |
| 92083 | Visual field examination(s) | 92133 | Cmptr ophth img optic nerve | | |
| 92235 | Eye exam with photos | 92250 | Eye exam with photos | | |
| 92083 | Visual field examination(s) | 92250 | Eye exam with photos | | |
| 92083 | Visual field examination(s) | 92134 | Cptr ophth dx img post segmt | | |
| 92134 | Cptr ophth dx img post segmt | 92235 | Eye exam with photos | | |
| 92134 | Cptr ophth dx img post segmt | 92250 | Eye exam with photos | | |
| 92134 | Cptr ophth dx img post segmt | 92235 | Eye exam with photos | 92250 | Eye exam with photos |
| 92250 | Eye exam with photos | 92285 | Eye photography | | |
| 92082 | Visual field examination(s) | 92250 | Eye exam with photos | | |
| 92081 | Visual field examination(s) | 92285 | Eye photography | | |

C. Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be comprised 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 (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 to 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 risk-of-service.

For CY 2013, 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 crosswalk(s) used for determining their malpractice RVUs in the final rule with comment period. The CY 2013 malpractice RVUs for new/revised codes will be implemented as interim final values in the CY 2013 PFS final rule with comment period, where they will be subject to public comment. They will then be finalized in the CY 2014 PFS final rule with comment period.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). 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 beginning January 1, 2011.

Section 1848 (e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2011. The statute was amended to extend the 1.0 floor for the work GPCIs through February 29, 2012 by section 303 of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) (Pub. L. 112-78). The statute was again amended by section 3004 of the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) (P.L. 112-399) to extend the 1.0 work floor for GPCIs throughout the remainder of CY 2012 (that is, for services furnished no later than December 31, 2012). During the development of the CY 2012 PFS final rule with comment period, neither TPTCCA nor MCTRJCA had been enacted and, because the work GPCI floor was set to expire at the end of 2011, the GPCIs published in Addendum E of the CY 2012 PFS final rule with comment period did not reflect the 1.0 work floor. Appropriate changes to the CY 2012 GPCIs were made to reflect the 1.0 work floor required by section 303 of the TPTCCA and section 3004 of the MCTRJCA.

Since the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act is set to

expire prior to the implementation of the CY 2013 PFS, the proposed CY 2013 work GPCIs and summarized geographic adjustment factors (GAFs) published in addendums D and E of this CY 2013 PFS proposed rule do not reflect the 1.0 work GPCI floor for CY 2013. As required by section 1848 (e)(1)(G) and section1848 (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 applicable in CY 2013.

In the CY 2012 PFS final rule with comment period we made several refinements to the GPCIs (76 FR 73081 through 73092), including revising the sixth GPCI update to reflect the most recent data, with modifications. Specifically, we finalized our proposal to change the GPCI cost share weights for CY 2012 to reflect the most recent rebased and revised Medicare Economic Index (MEI). As a result, the cost share weight for the work GPCI (as a percentage of the total) was updated from 52.466 percent to 48.266 percent, and the cost share weight for the PE GPCI was revised from 43.669 percent to 47.439 percent with a change in the employee compensation component from 18.654 to 19.153 percentage points. The cost share weight for the office rent component of the PE GPCI was changed from 12.209 percent to 10.223 percentage points (fixed capital with utilities), and the medical equipment, supplies, and other miscellaneous expenses component was updated to 9.968 percentage points. In addition, we finalized the weight for purchased services at 8.095 percentage points, of which 5.011 percentage points are adjusted for geographic cost differences. Lastly, the cost share weight for the MP GPCI was revised from 3.865 percent to 4.295 percent. Table 16 displays the cost share weights that were finalized in the CY 2012 final rule with comment period. Note that the employee compensation; office rent; purchased services; and equipment supplies and other cost share weights sum to the total PE GPCI cost share weights of 47.439 percent.

**TABLE 16: Cost Share Weights finalized in CY 2012 GPCI Update**

| Expense Category | Cost Share Weights % |
|---|---|
| Physician Work | 48.266 |
| Practice Expense | 47.439 |
| Employee Compensation | 19.153 |
| Office Rent | 10.223 |
| Purchased Services | 8.095 |
| Equipment, Supplies, and Other | 9.968 |
| Malpractice Insurance | 4.295 |

We also finalized several other policies including the use of 2006 through 2008 American Community Survey (ACS) two-bedroom rental data as a proxy for the relative cost difference in physician office rent. In addition, we created a purchased services index to account for labor-related services within the "all other services" and "other professional expenses" MEI components. In response to public commenters who recommended that we utilize Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data to capture the “full range” of occupations included in the offices of physician industry to calculate the nonphysician employee wage component (also referred to as the employee wage index) of the PE GPCI, we finalized a policy of using 100 percent of the total wage share of nonphysician occupations in the offices of physicians' industry to calculate the nonphysician employee wage component of the PE GPCI.

2. Recommendations from the Institute of Medicine

Concurrent with our CY 2012 rulemaking cycle, the Institute of Medicine released the final version of its first of two anticipated reports entitled “Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, Second Edition” on September 28, 2011. This report included an evaluation of the accuracy of geographic adjustment factors for the hospital wage index and the GPCIs, as well as the methodology and data used to calculate them. Several of the policies that we finalized in CY 2012 rulemaking addressed several of the recommendations

contained in the Institute of Medicine's first report. Because we did not have adequate time to completely address the Institute of Medicine's Phase I report recommendations during CY 2012 rulemaking, we have included a discussion in this proposed rule about the recommendations that were not implemented or discussed in the CY 2012 final rule with comment period. We look forward to receiving comments on these recommendations.

The Institute of Medicine's second report, expected in summer 2012, will evaluate the effects of geographic adjustment factors (hospital wage index and GPCIs) on the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. We did not receive the Institute of Medicine's Phase II report in time for consideration for this CY 2013 proposed rule. We intend to address the Institute of Medicine's recommendations in the Phase II report once we have had an opportunity to fully evaluate the report and its recommendations.

3. GPCI Discussion for CY 2013

CY 2013 is the final year of the sixth GPCI update and, because we will propose updates next year, we are not including any proposals related to the GPCIs in this proposed rule. In response to public inquiries about exceptions to the calculated GPCIs, we are providing a brief discussion about the permanent 1.0 PE floor for frontier States, the 1.5 work floor for Alaska, the GPCIs for the Puerto Rico payment locality, and the expiration of the GPCI 1.0 work floor required under section 1848 (e)(1)(E) of the Act. We also discuss recommendations from the first Institute of Medicine report that were not addressed during CY 2012 rulemaking in this proposed rule.

a. Alaska Work Floor and PE GPCI Floor for Frontier States

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. Therefore, the 1.5 work floor for Alaska will

remain in effect in CY 2013. In addition, section 1848(e) (1)(I) of the Act establishes 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. There are no proposed changes to those States identified as "Frontier States" for the CY 2013 proposed rule. The following States are considered to be "Frontier States" for CY 2013: Montana, North Dakota, Nevada, South Dakota, and Wyoming.

b. GPCI Assignments for the Puerto Rico Payment Locality

Recently, we have received inquiries from representatives of the Puerto Rico medical community regarding our policies for determining the GPCIs for the Puerto Rico payment locality. While we are not making any proposals related to the GPCIs for Puerto Rico, in response to those inquiries, we are providing the following discussion regarding the GPCIs assigned to the Puerto Rico payment locality. We anticipate recalculating all the GPCI's in the seventh GPCI update currently anticipated in CY 2014.

As noted above, we are required by section 1848(e)(1)(A) of the Act to develop separate GPCIs to measure relative resource cost differences among localities compared to the national average for each of the three fee schedule components: work, PE and malpractice expense. To calculate these GPCI values, we rely on three primary data sources. We currently use the 2006-2008 BLS OES data to calculate the work GPCI, the nonphysician employee wage component of PE GPCI, and the labor costs associated with the purchased services component of PE GPCI. We use 2006-2008 ACS data to calculate the office rent component of the PE GPCI. Finally, we use 2006-2007 malpractice premium data to calculate the MP GPCI. For all localities, including Puerto Rico, we assume equipment, supplies, and other expenses are purchased in a national market and that the costs do not vary by geographic location. Therefore,

we do not use data on the price of equipment, supplies, and expenses across localities in calculating PE GPCIs. With the exception of the MP GPCI, we have current data from the applicable sources allowing us to calculate the work and PE GPCIs for the Puerto Rico payment locality. The 2006-2008 BLS OES data and rental values derived from the 2006-2008 ACS indicate that the costs associated with operating a physician practice in Puerto Rico are the lowest among all payment localities.

In order to calculate the MP GPCI for the various Medicare PFS localities, we collect malpractice insurance market share and premium data from state departments of insurance and from state rate filings. As discussed in our contractor's report (Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule pg. 41), for the fourth, fifth, and sixth GPCI updates we were not able to collect this data for the Puerto Rico payment locality. Therefore, we carried over the MP GPCI value of 0.249 from previous GPCI updates when malpractice premium data were last available. It is important that we have a source for more current malpractice premium data for Puerto Rico for use in the upcoming seventh GPCI update. We are working with the relevant officials in Puerto Rico to acquire these data for use in future rulemaking. We would encourage comments from stakeholders regarding potential data sources that may be available for calculating the Puerto Rico malpractice GPCI. For a detailed discussion regarding the methodology used to calculate the various components of the Puerto Rico GPCIs, we refer readers to our contractor's report from November of 2010 entitled "Final Report on the Sixth Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule" available on our Website at http://www.cms.gov/PhysicianFeeSched/downloads/GPCI_Report.pdf.

c. Expiration of GPCI Work Floor

The work GPCIs are designed to capture the relative costs of physician labor by Medicare

PFS locality. Previously, the work GPCIs were developed using the median hourly earnings from the 2000 Census of workers in seven professional specialty occupation categories which we used as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories because Medicare payments are a key determinant of physicians' earnings. That is, including physicians' wages in the work GPCIs would effectively make the indices dependent upon Medicare payments. As required by law, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average. The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. For the sixth GPCI update in CY 2011, we used the 2006 through 2008 BLS OES data as a replacement for the 2000 Census data.

Although we are not proposing any changes to the data or methodology used to calculate the work GPCI for CY 2013, we note that addenda D and E will reflect the expiration of the statutory 1.0 work GPCI floor. As noted above, section 1848 (e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2011 until it was temporarily extended through February 29, 2012 by section 303 of the TPTCCA. The GPCI work floor was extended throughout the remainder of CY 2012 by section 3004 of the MCTRJCA.

4. Institute of Medicine Phase I Report

a. Background

At our request, the Institute of Medicine is conducting a study of the geographic adjustment factors in Medicare payment. It is a comprehensive empirical study of the geographic adjustment factors established under sections 1848(e) (GPCI) and 1886(d)(3)(E) of the Act (hospital wage index). These adjustments are designed to ensure Medicare payment fees and rates reflect differences in input costs across geographic areas. The factors the Institute of Medicine is evaluating include the following:

- Accuracy of the adjustment factors;
- Methodology used to determine the adjustment factors; and
- Sources of data and the degree to which such data are representative.

Within the context of the U.S. healthcare marketplace, the Institute of Medicine is also evaluating and considering the—

- Effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability of hospitals and other facilities to maintain an adequate and skilled workforce; and

++ Patient access to providers and needed medical technologies;

- Effect of adjustment factors on population health and quality of care; and
- Effect of the adjustment factors on the ability of providers to furnish efficient, high value care.

The Institute of Medicine's first report entitled "Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy" evaluated the accuracy of geographic adjustment factors and the methodology and data used to calculate them. The recommendations included in the Institute of Medicine's Phase I report that relate to or would have an effect on the methodologies used to calculate the GPCIs and the configuration of Medicare PFS payment locality structure are summarized as follows:

- Recommendation 2-1: The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.

- Recommendation 2-2: The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all health care employers.
- Recommendation 5-1: The GPCI cost share weights for adjusting fee-for-service payments to practitioners should continue to be national, including the three GPCIs (work, PE, and liability insurance) and the categories within the PE (office rent and personnel).
- Recommendation 5-2: Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified.
- Recommendation 5-3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process.
- Recommendation 5-4: The PE GPCI should be constructed with the full range of occupations employed in physicians' offices, each with a fixed national weight based on the hours of each occupation employed in physicians' offices nationwide.
- Recommendation 5-5 CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare & and Medicaid Services.
- Recommendation 5-6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot.
- Recommendation 5-7: Nonclinical labor-related expenses currently included under PE office expenses should be geographically adjusted as part of the wage component of the PE.

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

As previously noted, the Institute of Medicine will consider the role of Medicare

payments on matters such as the distribution of the healthcare workforce, population health, and the ability of providers to produce high-value, high-quality health care in its final report anticipated in summer 2012. We were not able to evaluate the recommendations contained in the Institute of Medicine's Phase II report, in time for discussion in this proposed rule.

b. Institute of Medicine Recommendations Implemented in CY 2012

In the CY 2012 final rule with comment period, we addressed three of the recommendations offered by the Institute of Medicine in their Phase I report. Specifically, the final CY 2012 GPCIs utilized the full range of non-physician occupations in the employee wage calculation consistent with Institute of Medicine recommendation 5-4. Additionally, we created a new purchased service index to account for non-clinical labor related expenses similar to Institute of Medicine recommendation 5-7. Lastly, we have consistently used national cost share weights to determine the appropriate weight attributed to each GPCI component, which is supported by Institute of Medicine recommendation 5-1 (76 FR 73081 through 73092). In order to facilitate a public discussion regarding the Institute of Medicine's remaining recommendations, we are providing a summary analysis of these recommendations in this proposed rule below. We will provide our technical analyses of the remaining Institute of Medicine Phase I recommendations in a report that will be released on the PFS Website at http://www.cms.gov/PhysicianFeeSched. Since we have not yet had an opportunity to review the recommendations in the Institute of Medicine's Phase II report, these analyses focus exclusively on the recommendations as presented in the Institute of Medicine's Phase I release.

c. Discussion of Remaining Institute of Medicine recommendations

(1) Institute of Medicine Recommendation Summaries

(A) Institute of Medicine recommendation 2-1: The same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor.

Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 2-1 thru 2-29)

(i) Locality 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 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, effective January 1, 1992. Payments under the fee schedule are based on the relative resources required to provide services and vary among areas as resource costs vary geographically as measured by the GPCIs.

Payment localities 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. As a result, a study was begun in 1994 which resulted in a comprehensive locality revision, which 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. A full discussion of the methodology can be found in 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 was stated in the CY 2011 final rule with comment period (75 FR 73261), we currently require that changes to the PFS locality structure be done in a budget neutral manner within a state. For many years, we have sought consensus for any locality changes among the professionals whose payments would be affected. We have also considered more comprehensive changes to locality configurations. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (http://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 their 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 difference 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," is accessible from the CMS PFS Web page under the heading "Review of Alternative GPCI Payment Locality Structures – Final Report." The report may also be accessed directly from the following link:

http://www.cms.gov/PhysicianFeeSched/downloads/Alt_GPCI_Payment_Locality_Structures_Review.pdf

(ii) Institute of Medicine Recommendation Discussion

The Institute of Medicine recommends altering the current locality structure that was originally based on areas set by local contractors and, in 1996, reduced from 210 to current 89 using a systematic iterative methodology. Rather than using the current uniform fee schedule areas in adjusting for relative cost differences as compared to the national average, the Institute of Medicine recommends a three-tiered system for defining fee schedule areas. In the first tier, the Institute of Medicine proposes applying county-based fee schedule areas to calculate the employee wage component of the PE GPCI. Although the Institute of Medicine's report states that it recommends that "Metropolitan statistical areas and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets," the Institute of Medicine also recommends applying an out-commuting adjustment, which would permit employee wage index values to vary by county. Since the employee wage index is one component of the PE GPCI, these values also would vary by county under the Institute of Medicine's proposal.

To understand why the employee wage index would vary by county under the Institute of Medicine's recommendation, consider the three steps that would be required to calculate the employee wage index. The first step calculates the average hourly wage (AHW) for workers employed in each MSA or residual (rest of state) area. The wages of workers in each occupation are weighted by the number of workers employed in physicians' offices nationally. The second step applies a commuting-based smoothing adjustment to create area index wages for each county. The commuting-adjusted county index wages are equal to a weighted average of the AHW values calculated in the first step, where the weights are county-to-MSA out-commuting patterns. The Institute of Medicine's out-commuting-based weights equal the share of health care workers that live in a county where a physician's office is located who commute out of the county to work in a physician office in each MSA. The third step sets each physician's employee index wage equal to the estimated area index wage (calculated in Step 2) of the county in which the physician office is located. Because the out-commuting adjustment envisioned by the Institute of Medicine in the second step varies by county, the employee wage index value—and thus the PE GPCI as a whole— would also potentially vary by county depending on the smoothing option chosen. If implemented, the number of employee wage index payment areas could potentially increase from 89 to over 3,000.

The Institute of Medicine's second tier of fee schedule areas would use an MSA-based approach. The Institute of Medicine proposes using the MSA-based system for the work GPCI, the office rent index, the purchased services index, and the MP GPCI. An MSA is made up of one or more counties, including the counties that contain the core urban area with a population of 50,000 or more, as well as surrounding counties that exhibit a high degree of social and economic integration (as measured by commuting patterns) with the urban core. MSAs are designed to be socially and economically integrated units based on the share of workers who

commute to work within the urban core of each MSA. Implementing an MSA-based locality structure would expand the number of fee schedule areas from 89 to upwards of 400 plus additional MSAs for U.S. territories (for example, Virgin Islands, American Samoa, Guam, Northern Marianna Islands).

In its third payment area tier, the Institute of Medicine proposes creating a national payment area for the "equipment, supplies and other" index. We currently do not adjust PEs associated with supplies and equipment since we believe they are typically purchased in a national market. Thus, this approach is equivalent to using a national fee schedule area to define this index. The Institute of Medicine proposes no change to the fee schedule area used to compute the "equipment, supplies and other" index.

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 three-tiered 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 reside within higher cost MSAs, would experience increases in their applicable GPCIs and GAFs.

The localities used to calculate the GPCIs have been a subject of substantial discussion and debate since the implementation of the PFS. The intensity of those discussions has increased since the last comprehensive update to the locality structure in 1997. Physicians and other suppliers in areas such as Santa Cruz County, California and Prince William County, Virginia have expressed concern that the current locality structure does not appropriately capture economic and demographic shifts that have taken place since the last PFS locality update. On the other hand, rural practitioners have argued that revisions to the current PFS payment

localities will reduce their payments and exacerbate the problems of attracting physicians and other practitioners to rural areas. In the past, we have also heard concerns from representatives of some statewide localities regarding the potential implications of adopting an alternative locality structure that would change their current statewide payment area (74 FR 33536).

The Institute of Medicine stated in its Phase I report regarding its locality recommendation that, "While the payment areas would stay the same for the HWI (hospital wage index), implementing this recommendation would mean that the GPCI payment areas would expand from 89 to 441 areas, which would be a significant change. The impact of the change in payment areas will be assessed in the Phase II report." ("Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy, Second Edition" on September 28, 2011 pg 5-6.) Moreover, the Institute of Medicine's Phase II report will evaluate the effects of geographic adjustment factors on the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Over the years, commenters that have opposed revisions to localities have claimed that changes to the PFS areas could have a significant impact on the ability of rural areas to attract physicians. Certainly, one of our major goals when we last comprehensively revised the Medicare PFS localities in 1996 was to avoid excessively large urban/rural payment differences (61 FR 59494). In 1996, we were hopeful that the revisions would improve access to care for rural areas (61 FR 59494). Some areas may have experienced both economic and demographic shifts since the last comprehensive locality update. Before moving forward with the Institute of Medicine's three tiered locality recommendation, or any other potential locality revision, we need to assess, and prepare to inform the public of, the impact of any change for all Medicare stakeholders. The Institute of Medicine's Phase II report, scheduled for release this summer 2012, should contain an evaluation of many of these important factors including:

● The effect of the adjustment factors on the level and distribution of the health care workforce and resources, including--

++ Recruitment and retention taking into account mobility between urban and rural areas;

++ Ability for hospitals and other facilities to maintain an adequate and skilled workforce;

++ Patient access to providers and needed medical technologies;

++ Effect of adjustment factors on population health and quality of care; and

++ Effect of adjustment factors on the ability of providers to furnish efficient, high value care.

To fully assess the broader public policy implications associated with the Institute of Medicine's locality recommendation, we must first fully assess and analyze the recommendations contained in the Institute of Medicine's phase II report. Accordingly, we believe that it would be premature to propose any change to the PFS localities at this time.

In conjunction with 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 (for example, Town Hall meetings or Open Door Forums), as well as opportunities for public comments afforded by the rulemaking process.

While we are making no proposal in this proposed rule to change the current locality configuration, we are seeking public comment regarding Institute of Medicine's recommended three-tiered PFS payment locality definition. In addition, we will make our technical analyses of the Institute of Medicine locality recommendations, specific to the Phase I report, available on the PFS Website at http://www.cms.gov/PhysicianFeeSched/.

(B) Institute of Medicine Recommendation 2-2: The data used to construct the hospital wage index and the physician geographic adjustment factor should come from all healthcare employers (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 2-1 thru 2-29) and; Recommendation 5-5 CMS and the Bureau of Labor Statistics should develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pg 5-38.)

The Institute of Medicine recommends altering the data used to calculate the employee wage index. Specifically, Institute of Medicine recommends using wage data for workers in the healthcare industry rather than wage data for workers across all-industries. Although all-industry wage data has the largest sample size, the Institute of Medicine "…is concerned that the [all-industry] sample does not represent physician offices." BLS OES occupation wage data by MSA, however, are not publicly available for the healthcare industry. Using healthcare-industry wages requires the use of confidential BLS OES data, to which CMS does not have access at this time. Although the Institute of Medicine recommends that CMS secure an agreement with BLS to use the confidential wage data, the current employee wage index relies on publicly-available all-industry wage data. We seek comment on the use of confidential employee wage index data rather than the publicly available all-industry wage data.

Regardless of whether healthcare-industry or all-industry wage data is used, the Institute of Medicine recommends following the current approach adopted by CMS in CY 2012 for calculating the employee wage index. This approach constructs the employee wage index as a weighted average of occupation wages for the full-range of occupations employed in physicians' offices, where the weights are equal to the fixed national weight based on the hours of each occupation employed in physicians' offices nationwide. We adopted this approach for

calculating the GPCI employee wage index in the CY 2012 PFS final rule with comment period (76 FR 73088).

(C) Institute of Medicine recommendation 5-2: Proxies should continue to be used to measure geographic variation in the physician work adjustment, but CMS should determine whether the seven proxies currently in use should be modified (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pg 5-36) and; Recommendation 5-3: CMS should consider an alternative method for setting the percentage of the work adjustment based on a systematic empirical process. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 5-36 thru 5-37)

The Institute of Medicine recommends replacing the current work GPCI methodology with a regression-based approach. We currently use three steps to calculate the work GPCI. These steps include:

(1) Selecting the proxy occupations and calculating an occupation-specific index for each proxy;

(2) Assigning weights to each proxy-occupation index based on the each occupation's share of total national wages to create an aggregate proxy-occupation index; and

(3) Adjusting the aggregate proxy-occupation index by a physician inclusion factor to calculate the final work GPCI.

By using this approach, the current methodology reduces the circularity problem that occurs when work GPCI values are based on direct measurements of physician earnings. Because physician earnings are made up of both wages and a return on investment from ownership of the physician practice, calculating the work GPCI using physician earnings information would assign areas where physician practices are more profitable higher work GPCI values. Although the Institute of Medicine recommends that we continue to use proxy

occupations in the work GPCI methodology, its regression-based approach alters each of the three steps described above.

To modify the first step, the Institute of Medicine recommends that we empirically evaluate the validity of seven proxy occupations we currently use. The current proxy occupations in the work GPCI are intended to represent highly educated, professional employee categories. Although the Institute of Medicine recommends re-evaluating the proxy occupations used in the work GPCI, it does not define specific criteria to use for this purpose.

To modify the second step, the Institute of Medicine recommends using a regression-based approach to weight the selected proxy occupation indices based on their correlation with physician earnings. This Institute of Medicine proposal would replace the current approach where occupations are weighted by the size of their share of total national wages. Such an approach presumes that wages for proxy occupations are not related to physician profits.

Finally, the Institute of Medicine proposes an empirically-based approach to determine the inclusion factor for work. The inclusion factor for work refers to section 1848(e)(1)(A)(iii) of the Act requiring that the work GPCI reflect only 25 percent of the difference between the relative value of physicians' work effort in each locality and the national average of such work effort. Therefore, under current law, only one quarter of the measured regional variation in physician wages is incorporated into the work GPCI. The Institute of Medicine recommends calculating an inclusion factor based on the predicted values of the regression described above. Under the Institute of Medicine's approach, the inclusion factor is larger when the proxy occupations have a higher correlation with physicians' earnings and smaller when the proxy occupations have a lower correlation with physicians' earnings. We note that using such an empirical approach to weight the proxy occupation indices and to estimate the inclusion factor requires the identification of a viable source of physician wage information in addition to the

wage information of proxy occupations to accurately measure regional variation in physician wages.

We seek comment on the Institute of Medicine recommendations to revise the work GPCI methodology. In addition, we look forward to the MedPAC study on this issue required under section 3004 of the MCTRJCA. This study will assess whether any geographic adjustment to physician work is appropriate and, if so, what the level should be and where it should be applied.

(D) Institute of Medicine Recommendation 5-6: A new source of information should be developed to determine the variation in the price of commercial office rent per square foot. (Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy pages 5-38 thru 5-39)

The Institute of Medicine recommends the development of a new source of data to determine the variation in the price of commercial office rent per square foot. However, the Institute of Medicine does not explicitly recommend where the data should come from or how it should be collected. Before coming to this recommendation, the Institute of Medicine identified and evaluated several public and commercially available sources of data to determine whether an accurate alternative is available to replace the residential rent data currently used as a proxy to measure regional variation in physicians' cost to rent office space in the PE GPCI; these sources include rental data from the U.S. Department of Housing and Urban Development, American Housing Survey, General Services Administration, Basic Allowance for Housing (U.S. Department of Defense), U.S. Postal Service, Medical Group Management Association (MGMA), and REIS, Inc. The Institute of Medicine concluded that these sources had substantial limitations, including lack of representativeness of the market in which physicians rent space, small sample size, low response rates, and sample biases. Although we agree that a suitable

source for commercial office rent data would be preferable to the use of residential rent data in our PE office rent methodology, we have still been unable to identify an adequate commercial rent source that sufficiently covers rural and urban areas. We will continue to evaluate possible commercial rent data sources for potential use in the office rent calculation. We also encourage public commenters to notify us of any publicly available commercial rent data sources, with adequate data representation of urban and rural areas that could potentially be used in the calculation of the office rent component of PE.

E. 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, or electrocardiogram, or 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 which 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 (Pub. L. 106-554) (BIPA) added a new 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 the practitioner at the distant site. 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 does allow the use of asynchronous "store-and-forward" technology in delivering these services 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 individual 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 hospital-based renal dialysis centers, skilled nursing facilities (SNFs), and community mental health centers (CMHCs). In order to serve as a telehealth originating site, these sites must be located in an area designated as a rural health professional shortage area (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 of Health and Human Services as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be presented by a practitioner 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 an 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. In general, originating sites must be located in a rural HPSA or in a county outside of an MSA. 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); and
- Smoking cessation services.

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 of Health and Human Services 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). .

2. Requests for 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 in order 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), and smoking cessation services.

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 2012 will be considered for the CY 2014 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 Website at www.cms.gov/telehealth/.

3. Submitted Request and Other Additions to the List of Telehealth Services for CY 2013

We received a request in CY 2011 to add alcohol and/or substance abuse and brief intervention services as Medicare telehealth services effective for CY 2013. The following presents a discussion of this request, and our proposals for additions to the CY 2013 telehealth list.

a. Alcohol and/or Substance Abuse and Brief Intervention Services

The American Telemedicine Association submitted a request to add alcohol and/or substance abuse and brief intervention services, reported by CPT codes 99408 (Alcohol and/or substance (other than tobacco) abuse structured screening (for example, AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes) and 99409 (Alcohol and/or substance (other than tobacco) abuse structured screening (for example, AUDIT, DAST), and brief intervention

(SBI) services; greater than 30 minutes) to the list of approved telehealth services for CY 2013 on a category 1 basis.

We note that we assigned a status indicator of ‘‘N’’ (Noncovered) to CPT codes 99408 and 99409 as explained in the CY 2008 PFS final rule with comment period (72 FR 66371). At the time, we stated that because Medicare only provides payment for certain screening services with an explicit benefit category, and these CPT codes incorporate screening services along with intervention services, we believed that these codes were ineligible for payment under the PFS. We continue to believe that these codes are ineligible for payment under PFS and, additionally, under the telehealth benefit. We do not believe it would be appropriate to make payment for claims using these CPT codes for the services furnished via telehealth, but not when furnished in person. Because CPT codes 99408 and 99409 are currently assigned a noncovered status indicator, and because we continue to believe this assignment is appropriate, we are not proposing to add these CPT codes to the list of Medicare Telehealth Services for CY 2013.

However, we created two parallel G-codes for 2008 that allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not furnished as screening services, but that are furnished in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (for example, AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397, (Alcohol and/or substance (other than tobacco) abuse structured assessment (for example, AUDIT, DAST) and intervention greater than 30 minutes). Since these codes are used to report comparable alcohol and substance abuse services under certain conditions, we believe that it would be appropriate to consider the ATA’s request as it applies to these services when appropriately reported by the G-codes. The ATA asked that CMS consider this request as a category 1 addition based on the similarities between

these services and CPT codes 99406 (Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes) and 99407 (Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes). We agree that the interaction between a practitioner and a beneficiary receiving alcohol and substance abuse assessment and intervention services is similar to their interaction in smoking cessation services. We also believe that the interaction between a practitioner and a beneficiary receiving alcohol and substance abuse assessment and intervention services is similar to the assessment and intervention elements of CPT code 96152 (health and behavior intervention, each 15 minutes, face-to-face; individual), which also is currently on the telehealth list.

Therefore, we are proposing to add HCPCS codes G0396 and G0397 to the list of telehealth services for CY 2013 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 alcohol and substance abuse assessment and intervention services as Medicare telehealth services.

b. Preventive Services

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.

During CY 2012, CMS added coverage for several preventive services through the national coverage determination (NCD) process as authorized by section 1861(ddd) of the Act. These services add to Medicare's existing portfolio of preventive services that are now available

without cost sharing under the Affordable Care Act. We believe that for several of these services, the interactions between the furnishing practitioner and the beneficiary are similar to services currently on the list of Medicare telehealth services. Specifically, we believe that the assessment, education, and counseling elements of the following services are similar to existing telehealth services:

- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse, reported by HCPCS codes G0442 (Annual alcohol misuse screening, 15 minutes) and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes).
- Screening for depression in adults, reported by HCPCS code G0444 (Annual Depression Screening, 15 minutes).
- Screening for sexually transmitted infections (STIs) and high-intensity behavioral counseling (HIBC) to prevent STIs, reported by HCPCS code G0445 (High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes).
- Intensive behavioral therapy for cardiovascular disease, reported by HCPCS code G0446 (Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes).
- Intensive behavioral therapy for obesity, reported by HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes). We believe that the interactions between practitioners and beneficiaries receiving these services are similar to individual KDE services reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour), individual MNT reported by HCPCS code G0270 (Medical nutrition therapy; reassessment and subsequent intervention(s) following second

referral in the same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face-to-face with the patient, each 15 minutes); CPT code 97802 (Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes); and CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes), and HBAI reported by CPT code 96150 (Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment); CPT code 96151 (Health and behavior assessment (for example, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient re-assessment); CPT code 96152 (Health and behavior intervention, each 15 minutes, face-to-face; Individual); CPT code 96153 (Health and behavior intervention, each 15 minutes, face-to-face; Group (2 or more patients)); CPT code 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)), all services that are currently on the telehealth list.

Therefore, we are proposing to add HCPCS codes G0442, G0443, G0444, G0445, G0446, and G0447 to the list of telehealth services for CY 2013 on a category 1 basis. We note that all coverage guidelines specific to the services would continue to apply when these services are furnished via telehealth. For example, when the national coverage determination requires that the service be furnished to beneficiaries in a primary care setting, the qualifying originating telehealth site must also qualify as a primary care setting. Similarly, when the national coverage determination requires that the service be furnished by a primary care practitioner, the qualifying primary distant site practitioner must also qualify as primary care practitioner. For more detailed

information on coverage requirements for these services, we refer readers to the Medicare National Coverage Determinations Manual, Pub. 100-03, Chapter 1, Section 210, available at http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf. Consistent with this proposal, we are also proposing to revise our regulations at §410.78(b) and §414.65(a)(1) to include these preventive services as Medicare telehealth services.

4. Technical Correction to Include Emergency Department Telehealth Consultations in Regulation

In the CY 2012 PFS final rule with comment period (76 FR 73103), we finalized our proposal to change the code descriptors for initial inpatient telehealth consultation G-codes to reflect telehealth consultations furnished to emergency department patients in addition to inpatient telehealth consultations effective January 1, 2012. However, we did not amend the description of the services within the regulation at §414.65(a)(1)(i). Therefore, we are proposing to make a technical revision to our regulation at §414.65(a)(1)(i) to reflect telehealth consultations furnished to emergency department patients in addition to hospital and SNF inpatients.

F. Extension of Payment for Technical Component of Certain Physician Pathology Services

1. Background and Statutory Authority

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provided payment to independent laboratories furnishing the technical component (TC) of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for a 2-year period beginning on January 1, 2000. This section has been amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), section 104 of division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), section 3104 of the Affordable Care Act (Pub. L. 111–148), section 105 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309), section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112-78) and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96) to continue payment to independent laboratories furnishing the technical component (TC) of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for various time periods. As discussed in detail below, Congress most recently acted to continue this payment through June 30, 2012. The TC of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist interprets. The professional component (PC) of physician pathology services refers to the pathologist's interpretation of the slide.

When the hospital pathologist furnishes the PC service for a hospital patient, the PC service is separately billable by the pathologist. When an independent laboratory's pathologist

furnishes the PC service, the PC service is usually billed with the TC service as a combined or global service.

Historically, any independent laboratory could bill the Medicare contractor under the PFS for the TC of physician pathology services for hospital patients even though the payment for the costs of furnishing the pathology service (but not its interpretation) was already included in the bundled inpatient stay payment to the hospital. In the CY 2000 PFS final rule with comment period (64 FR 59408 and 59409), we stated that this policy has contributed to the Medicare program paying twice for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) To the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. While the policy also permits the independent laboratory to bill for the TC of physician pathology services for hospital outpatients, in this case, there generally would not be duplicate payment because we would expect the hospital to not also bill for the pathology service, which would be paid separately to the hospital only if the hospital were to specifically bill for it. We further indicated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to its inpatients.

Therefore, in the CY 2000 PFS final rule with comment period, we revised §415.130(c) to state that for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC of physician pathology services furnished to a hospital inpatient. Ordinarily, the provisions in the PFS final rule with comment period are implemented in the following year. However, the change to §415.130 was delayed 1-year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Full implementation of §415.130 was further delayed by section 542 of the BIPA and

section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively. In the CY 2007 PFS final rule with comment period (71 FR 69788), we amended §415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA–TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first 6 months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Section 3104 of the Affordable Care Act amended the prior legislation to extend the payment through CY 2010. Section 105 of the MMEA extended the payment through CY 2011. Subsequent to publication of the CY 2012 PFS final rule with comment period, section 305 of the Temporary Payroll Tax Cut Continuation Act of 2011 extended the payment through February 29, 2012 and section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 extended the payment through June 30, 2012.

2. Revisions to Payment for TC of Certain Physician Pathology Services

In the CY 2012 PFS final rule with comment period, we finalized our policy that an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished after December 31, 2011, to a hospital inpatient or outpatient (76 FR 73278 through 73279, 73473). As discussed above, subsequent to publication of this final rule with comment period, Congress acted to continue payment to independent laboratories through June 30, 2012. Therefore, the policy that we finalized in the CY 2012 PFS final rule with comment period is superseded by statute for six months. To be consistent with the statutory changes and

our current policy, we are proposing conforming changes to §415.130(d) such that we will continue payment under the PFS to independent laboratories furnishing the TC of physician pathology services to fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital on or before June 30, 2012. Independent laboratories may not bill the Medicare contractor for the TC of physician pathology services furnished after June 30, 2012, to a hospital inpatient or outpatient.

G. Therapy Services

1. Outpatient Therapy Caps for CY 2013

Section 1833(g) of the Act applies annual, per beneficiary, limitations (therapy caps) on expenses incurred for outpatient therapy services under Medicare Part B. There is one therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined and a second separate therapy cap for outpatient occupational therapy (OT) services. Although therapy services furnished in an outpatient hospital setting have been exempt from the application of the therapy caps, section 3005(b) of the MCTRJCA amended section 1833(g) of the Act to require therapy services furnished in an outpatient hospital setting during 2012 be subject to the therapy caps beginning not later than October 1, 2012.

The therapy caps amount for CY 2013 will be announced in the CY 2013 PFS final rule with comment period. The annual change in each therapy cap is computed by multiplying the cap amount for CY 2012, which is $1,880, by the MEI for CY 2013, then rounding to the nearest $10. This amount is added to the CY 2012 therapy cap amount to obtain the CY 2013 therapy cap amount.

An exceptions process to the therapy caps has been in effect since January 1, 2006 -- originally authorized by section 5107 of the DRA, which amended section 1833(g)(5) of the Act. Since that time, the exceptions process for the therapy caps has been extended through

subsequent legislation (MIEA-TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, and TPTCCA). Last amended by section 3005 of the MCTRJCA, the Agency's authority to provide for an exception process to therapy caps expires on December 31, 2012. To request an exception to the therapy caps, therapy suppliers and providers use the KX modifier on claims for services that are over the cap amount. Use of the KX modifier indicates that the services are reasonable and necessary and that there is documentation of medical necessity in the beneficiary's medical record.

Section 3005 of the MCTRJCA also requires two additional changes to Medicare policies for outpatient therapy services. Section 3005(a)(5) adds a new subparagraph (C) to section 1833(g)(5) of the Act, effective October 1 through December 31, 2012, that requires application of a manual medical review process (similar to the process used in 2006 for certain therapy cap exceptions) for exceptions to the therapy caps after expenses incurred for the beneficiary's therapy services (including services furnished in a hospital outpatient department) exceed the threshold of $3,700 for the year. As with the therapy caps, there are two separate thresholds for the manual medical review process – one threshold of $3,700 for PT and SLP services combined and one threshold of $3,700 for OT services. Requests for exceptions to the therapy caps for services above the thresholds are subject to a manual medical review process. The applicable amount of expenses incurred for therapy services counted towards these thresholds for the year begins on January 1, 2012. Since the exceptions process is set to expire on December 31, 2012, the requirement for a manual medical review process will also expire then.

Section 3005(c) adds a new section 1842(t)(2) to the Act, effective beginning on October 1, 2012, that requires the National Provider Identifier (NPI) of the physician (or NPP, where applicable), who periodically reviews the therapy plan of care, to be reported on the claim

for therapy services. This reporting requirement applies to all claims for outpatient therapy services.

2. Claims-Based Data Collection Strategy for Therapy Services

a. Introduction

Section 3005(g) of the MCTRJCA requires CMS to implement, beginning on January 1, 2013, ". . . a claims-based data collection strategy that is designed to assist in reforming the Medicare payment system for outpatient therapy services subject to the limitations of section 1833(g) of the Act. Such strategy shall be designed to provide for the collection of data on patient function during the course of therapy services in order to better understand patient condition and outcomes."

b. History/Background

In 2010, more than 7.6 million Medicare beneficiaries received outpatient therapy services, including physical therapy (PT), occupational therapy (OT), and speech-language-pathology (SLP). Medicare payments for these services exceeded $5.6 billion. Between 1998–2008, Medicare expenditures for outpatient therapy services increased at a rate of 10.1 percent per year while the number of Medicare beneficiaries receiving therapy services only increased by 2.9 percent per year. Although a significant number of Medicare beneficiaries benefit from therapy services, the rapid growth in Medicare expenditures for these services has long been of concern to the Congress and the Agency. To address this concern, efforts have been focused on developing Medicare payment incentives that encourage delivery of reasonable and necessary care while discouraging overutilization of therapy services and the provision of medically unnecessary care. A brief review of these efforts is useful in understanding our proposal for CY 2013.

(1) Therapy Caps

Section 4541 of the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA) amended section 1833(g) of the Act to impose financial limitations on outpatient therapy services (the "therapy caps" discussed above) in an attempt to limit Medicare expenditures for therapy services. Prior to the BBA amendment, these caps had applied to services furnished by therapists in private practice, but the BBA expanded the caps effective January 1, 1999, to include all outpatient therapy services except those furnished in outpatient hospitals. Since that time, the Congress has amended the statute several times to impose a moratorium on the application of the caps or has required us to implement an exceptions process for the caps. The therapy caps have only been in effect without an exceptions process for less than two years. (See the discussion about the therapy cap exceptions process above.) Almost from the inception of the therapy caps, the Congress and the Agency have been exploring potential alternatives to the therapy caps.

(2) Multiple Procedure Payment Reduction (MPPR)

In the CY 2011 PFS final rule with comment period (75 FR 73232-73242), we adopted a MPPR of 25 percent applicable to the practice expense (PE) component of the second and subsequent therapy services when more than one of these services is furnished in a single session. This reduction applies to nearly 40 therapy services. (For a list of therapy services to which this policy applies, see Addenda H.) The Physician Payment and Therapy Relief Act of 2010 (PPTRA) subsequently revised the reduction to 20 percent for services furnished in an office setting, leaving the 25 percent reduction in place for services furnished in institutional settings. We adopted this MPPR as part of our directive under section 1848(c)(2)(k) of the statute (as added by section 3134(a) of the Affordable Care Act) to identify and evaluate potentially misvalued codes. By taking into consideration the expected efficiencies in direct PE resources that occur when services are furnished together, this policy results in more appropriate

payment for therapy services. Although we did not adopt this MPPR policy specifically as an alternative to the therapy caps, paying more appropriately for combinations of therapy services that are commonly furnished in a single session reduces the number of beneficiaries impacted by the therapy caps in a given year. For more details on the MPPR policy, see section II.C.4. of this proposed rule.

(3) Studies Performed

A uniform dollar value therapy cap sets a limit on the volume of services furnished unrelated to the specific services furnished or the beneficiary's condition or needs. One uniform cap does not deter unnecessary care or encourage efficient practice for low complexity beneficiaries. In fact, it may even encourage the provision of services up to the level of the cap. Conversely, a uniform cap without an exceptions process restricts necessary and appropriate care for certain high complexity beneficiaries. Recognizing these limitations in a uniform dollar value cap, we have been studying therapy practice patterns and exploring ways to refine payment for these services as an alternative to therapy caps.

On November 9, 2004, the Secretary delivered the Report to Congress, as required by the BBA as amended by the BBRA, "Medicare Financial Limitations on Outpatient Therapy Services." That report included two utilization analyses. Although these analyses provided details on utilization, neither specifically identified ways to improve therapy payment. In the report, we indicated that further study was underway to assess alternatives to the therapy caps. The report and the analyses are available on the CMS Website at http://www.cms.gov/TherapyServices/.

Since 2004, we have periodically updated the utilization analyses and posted other reports on the CMS Website to respond to the additional BBRA requirements. Subsequent reports highlighted the expected effects of limiting services in various ways and presented plans

to collect data about beneficiary condition, including functional limitations, using available tools. Through these efforts, we have made progress in identifying the outpatient therapy services that are billed to Medicare, the demographics of the beneficiaries who utilize these services, the types of therapy services furnished, the HCPCS codes used to bill the services, the allowed and paid amounts of the services, the providers of these services, the states in which the services are furnished and the type of practitioner furnishing services.

From these and other analyses in our ongoing research effort, we have concluded that without the ability to define the services that are typically needed to address specific clinical cohorts of beneficiaries (those with similar risk-adjusted conditions), it is not possible to develop payment policies that encourage the delivery of reasonable and necessary services while discouraging the provision of services that do not produce a clinical benefit. Although there is widespread agreement that beneficiary condition and functional limitations are critical to developing and evaluating an alternative payment system for therapy services, a system for collecting such data does not exist. Diagnosis information is available from Medicare claims. However, we believe that the primary diagnosis on the claim is a poor predictor for the type and duration of therapy services required. Much additional work is needed to develop an appropriate system for classifying clinical cohorts.

A 5-year CMS project titled "Development of Outpatient Therapy Payment Alternatives" (DOTPA) is expected to provide some of this information. The project is now in its final stages of data collection. The purpose of the DOTPA project is to identify a set of measures that we could routinely and reliably collect in support of payment alternatives to the therapy caps. Specifically, the measures being collected are to be assessed in terms of their administrative feasibility and their usefulness in identifying beneficiary need for outpatient therapy services and the outcomes of those services. A final report is expected during the second half of CY 2013. In

addition to developing alternatives to the therapy caps, the DOTPA project reflects our interest in value-based purchasing by identifying components of value, namely, beneficiary need and the effectiveness of therapy services. Although we expect DOTPA to provide meaningful data and practical information to assist in developing improved methods of paying for appropriate therapy services, DOTPA will not deliver a standardized measurement instrument for use in outpatient therapy services. Further, it is unlikely that this one project alone will provide adequate information to implement a new payment system for therapy. This study combined with data from a wider group of Medicare beneficiaries would enhance our ability to develop alternative payment policy for outpatient therapy services.

c. Proposal

(1) Overview

As required by section 3005(g) of MCTRJCA, we are proposing to implement a claims-based data collection strategy on January 1, 2013. This claims-based data collection system is designed to gather information on beneficiary function and condition, therapy services furnished, and outcomes achieved. This information will assist in reforming the Medicare payment system for outpatient therapy services. By collecting data on beneficiary function over an episode of therapy services, we hope to better understand the Medicare beneficiary population that uses therapy services, how their functional limitations change as a result of therapy services, and the relationship between beneficiary functional limitations and furnished therapy services over an episode of care. The term "functional limitation" generally encompasses both the terms "activity limitations" and "participation restrictions" as described by the International Classification of Functioning, Disability and Health (ICF). (For information on ICF, see http://www.who.int/classifications/icf/en/ and for specific ICF nomenclature (including activity limitations and participation restrictions), see http://apps.who.int/classifications/icfbrowser/.)

We are proposing to encompass, under this proposal, the Medicare Part B outpatient therapy benefit and PT, OT, and SLP under the Comprehensive Outpatient Rehabilitation Facilities (CORF) benefit. "Incident to" therapy services furnished by physicians or nonphysician practitioners (NPPs) would also be included. This broad applicability would include services furnished in hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), CORFs, rehabilitation agencies, and home health agencies (when the beneficiary is not under a home health plan of care) and private offices.

When used in this section "therapists" means all practitioners who furnish outpatient therapy services, including physical therapists, occupational therapists, and speech-language pathologists in private practice and those therapists who furnish services in the institutional settings, physicians and NPPs (including, physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), as applicable.)

This proposal is based upon an option for claims-based data collection that was discussed during the CY 2011 rulemaking (75 FR 40096 through 40100 and 73284 through 73293). This option was developed under a contract with CMS as part of the Short Term Alternatives for Therapy Services (STATS) project. The STATS project provided three options for alternative payment to the therapy caps that could be considered in the short-term before completion of the DOTPA project. In developing options, the STATS project drew upon the analytical expertise of CMS contractors and the clinical expertise of various outpatient therapy stakeholders to consider policies and available claims data. The options developed were:

- Capturing additional clinical information regarding the severity and complexity of beneficiary functional impairments on therapy claims in order to facilitate medical review and at the same time gather data that would be useful in the long term to develop a better payment mechanism;

- Introducing additional claims edits regarding medical necessity, in order to reduce overutilization; and
- Adopting a per-session bundled payment that would vary based on beneficiary characteristics and the complexity of evaluation and treatment services furnished in a session.

While we did not propose to adopt any of these alternatives at that time, we discussed these three options during the CY 2011 rulemaking and solicited public comments on all aspects of these alternatives, including the potential associated benefits or problems, clinical concerns, practitioner administrative burden, consistency with other Medicare and private payer payment policies, and claims processing considerations. In general, public commenters on the data collection effort questioned the ability to collect the needed information using this type of system. Commenters raised specific concerns about the training and education of therapists that would be needed prior to implementation. Although concerns were expressed about claims-based data reporting, no one questioned the need for data on beneficiary condition and functional limitations. The Congress has now included in section 3005(g) of the MCTRJCA a requirement to implement a claims-based data collection effort. While the proposed system is based upon the data collection alternative discussed in the CY 2011 PFS rulemaking, it has been modified in response to the comments received on the CY 2011 proposed rule.

The long-term goal is to develop an improved payment system for Medicare therapy services. The desired payment system would pay appropriately and similarly for efficient and effective services furnished to beneficiaries with similar conditions and functional limitations who have good potential to benefit from the services furnished. Importantly, such a system would not encourage the furnishing of medically unnecessary or excessive services. At this time, the data on Medicare beneficiaries' use and benefit from therapy services from which to develop an improved system does not exist. This proposed data collection effort would be the first step

towards collecting the data needed for this type of payment reform. Once the initial data have been collected and analyzed, we expect to be able to identify gaps in information and determine what additional data are needed to develop a new payment policy. Without a better understanding of the diversity of beneficiaries receiving therapy services and the variations in type and volume of treatments provided, we lack the information to develop a comprehensive strategy to map the way to an improved payment policy. While this claims-based data collection proposal is only the first step in a long-term effort, it is an essential step.

We are proposing to require that claims for therapy services include nonpayable G-codes and modifiers. Through the use of these codes and modifiers, we would capture data on the beneficiary's functional limitations (a) at the outset of the therapy episode, (b) at specified points during treatment and (c) at discharge from the outpatient therapy episode of care. In addition, the therapist's projected goal for functional status at the end of treatment would be reported on the first claim for services and periodically throughout an episode of care.

Specifically, G-codes would be used to identify what is being reported – current status, goal status or discharge status. Modifiers would indicate the extent of the severity/complexity of the functional limitation being tracked. The difference between the reported functional status at the start of therapy and projected functional status at the end of the course of therapy represents the progress the therapist anticipates the beneficiary would make during the course of treatment/episode of care. As the beneficiary progresses through the course of treatment, one would expect progress toward the goal established by the therapist.

By tracking changes in functional limitations throughout the therapy episode and at discharge, we would have information about the furnished therapy services and the outcomes of such services. The ICD-9 diagnosis codes reported on the claim form would provide information on beneficiary condition.

Since 2006, we have paid claims for therapy services that exceed the annual per beneficiary caps when the claims include the KX modifier. The presence of the KX modifier on a therapy claim indicates that the therapist attests that the services on the claim are medically necessary and that the justification for medical necessity is documented in the beneficiary's medical record. We propose to apply the additional G-code and modifier reporting requirements to all claims, including claims with the KX modifier and those subject to any manual medical review process, if such manual medical review or the KX modifier were applicable, after December 31, 2012. (See the discussion about therapy caps above.)

(2) Proposed Nonpayable G-Codes on Beneficiary Functional Status

For the proposed reporting, therapists would report G-codes and modifiers on Medicare claims for outpatient therapy services. Table 17 shows the proposed G-codes and their definitions. (An appropriate status indicator will be assigned to these codes if finalized.)

**TABLE 17: Proposed Nonpayable G-Codes for Reporting Functional Limitations.**

| Functional limitation for primary functional limitation | | |
|---|---|---|
| GXXX1 | Primary Functional limitation | Current status at initial treatment/episode outset and at reporting intervals |
| GXXX2 | Primary Functional limitation | Projected goal status |
| GXXX3 | Primary Functional limitation | Status at therapy discharge or end of reporting |
| Functional limitation for a secondary functional limitation if one exists | | |
| GXXX4 | Secondary Functional limitation | Current status at initial treatment/outset of therapy and at reporting intervals |
| GXXX5 | Secondary Functional limitation | Projected goal status |
| GXXX6 | Secondary Functional limitation | Status at therapy discharge or end of reporting |
| Provider attestation that functional reporting not required | | |
| GXXX7 | | Provider confirms functional reporting not required |

The proposed claims-based data collection system using G-codes and severity modifiers builds upon current Medicare requirements for therapy services. Section 410.61 requires that a

therapy plan of care (POC) be established before treatment begins. This POC must include: the type, amount, frequency, and duration of the PT, OT, SLP services to be furnished to each beneficiary, the diagnosis and the anticipated goals. Section 410.105(c) contains similar requirements for services furnished in the CORF setting. We have long encouraged therapists, through our manual provisions, to express the POC-required goals for each beneficiary in terms that are measureable and relate to identified functional impairments. See Pub 100-02, Chapter 15, Section 220.1.2. The evaluation and the goals developed as part of the POC would be the foundation for the initial reporting under the proposed system.

Using the first set of G-codes (GXXX1, GXXX2, and GXXX3) with appropriate modifiers, the therapist would report the beneficiary's primary functional limitation or the most clinically relevant functional limitation at the time of the initial therapy evaluation and the establishment of the POC. In combination with appropriate modifiers, these G-codes would describe the current functional limitation (GXXX1) and the projected goal (GXXX2) for the functional limitation and the status at the end of a course of therapy (GXXX3). At specified intervals during treatment, claims would also include GXXX1 to show the status at that time and GXXX2 to show the goal, which would not change during therapy, except as described below. At the time the beneficiary is discharged from therapy, the final claim for this episode of care would use GXXX2 to show the goal and GXXX3 to denote status at the end of reporting for this functional limitation.

Therapists frequently use measurement tools to quantify beneficiary function. The Patient Inquiry by Focus on Therapeutic Outcomes, Inc (FOTO) and the National Outcomes Measurement System (NOMS) by the American Speech-Language-Hearing Association (ASHA) are two such assessment tools in the public domain that can be used to determine a composite or overall score for an assessment of beneficiary function. Therapists could use the score produced

by such measurement tools, provided they are valid and reliable, to select the appropriate modifier for reporting the beneficiary's functional status. While we support the use of consistent, objective tools to determine beneficiary functional limitation, for several reasons, at this time we are not endorsing, nor are we proposing to require, use of a particular tool to determine the severity modifier discussed in the next section. Some tools are proprietary, and others in the public domain cannot be modified to explicitly address this data collection project. Further, this data collection effort spans several therapy disciplines. Requiring a specific instrument could create burdens for therapists that would have to be considered in light of any potential improvement in data accuracy, consistency and appropriateness that such an instrument would generate. We may reconsider this decision once we have more experience with claims-based data collection on beneficiary function associated with furnished therapy services. We are seeking public comment on the use of assessment tools. In particular, we are interested in feedback regarding the benefits and burdens associated with use of a specific tool to assess beneficiary functional limitations. We request that those favoring a requirement to use a specific tool provide information on the preferred tool and describe why the tool is preferred.

Early results from the DOTPA project suggest that most beneficiaries have more than one functional limitation at treatment outset. In fact, only 21 percent of the DOTPA assessments reported just one functional limitation. Slightly more than half (54 percent) reported two, three or four functional limitations.

To the extent that the DOTPA experience is typical, the therapist may need to make a determination as to which functional limitation is primary for reporting purposes. In cases where this is unclear, the therapist may choose the functional limitation that is most clinically relevant to a successful outcome for the beneficiary, the one that would yield the quickest and greatest mobility, or the one that is the greatest priority for the beneficiary. In all cases, this primary

functional limitation should reflect the predominant limitation that the furnished therapy services are intended to address.

To allow for more complete reporting, the second set of G-codes in Table 17 could be used to describe a secondary functional limitation, when one exists. Two examples demonstrate the applicability of the second set of G-codes.

(1) A beneficiary under a PT plan of care is being treated simultaneously for mobility restriction, for example, "walking and moving" (including, for example, climbing stairs) due to complications following a total knee replacement and for a "self-care" restriction due to a stabilized and immobilized upper extremity after a shoulder dislocation.

(2) A beneficiary under a SLP plan of care may be treated simultaneously for both a swallowing dysfunction and a communication impairment resulting from a stroke.

This secondary G-code set is used to report the functional limitation that the therapist considers secondary to the primary one at the outset of a course of therapy. For example, in the first scenario above, the therapist determines the "self-care" to be secondary to the beneficiary's primary one ("walking and moving"). The therapist would report the secondary functional limitation using a current status (GXXX4) along with the associated goal ( GXXX5).

In some cases, a secondary functional limitation may not develop or be identified until after the course of treatment has begun. In such situations, the therapist would begin reporting this secondary set at the time the functional limitation is identified. Just as in the example above, the therapist would report GXXX4 and GXXX5.

For beneficiaries having more than two functional limitations, once the goal for the primary functional limitation has been reached or the beneficiary's potential to reach the goal has been maximized, the reporting on that functional limitation ends and reporting can begin on a new functional limitation. The therapist would use the set of G-codes (and associated modifiers)

for the primary functional limitation, that is, GXXX1 - GXXX3, to report functional status of the beneficiary's third functional restriction. This process of adding a new functional limitation, for example, for the fourth and the fifth, can continue until therapy ends. Following this process, the set of G-codes that the therapist uses originally to report each functional limitation does not change throughout the episode of care, even though the originally reported secondary functional limitation (reported with GXXX4 through GXXX6) may have become the primary one, for clinical purposes, once the goal for the originally reported primary functional limitation was reached. The therapist is not expected to change the G-code set used originally to report a particular functional limitation; we believe requiring therapists to do so would be too burdensome and would confuse the data we are collecting for programmatic purposes.

We are seeking comment on specific issues regarding reporting data on a secondary limitation. Specifically, we request comments regarding whether reporting on secondary functional limitations should be required or optional. We would also be interested in information regarding what percentage of Medicare therapy beneficiaries has more than one functional limitation at the outset of therapy, and for those with multiple functional limitations, what is the average number. We would also be interested in information on the percentage of these functional limitations for which therapists go on to measure, document, and develop related therapy goals.

The proposed G-codes differ from the three separate pairs of G-codes discussed in the CY 2011 PFS rulemaking. The CY 2011 discussion included these three pairs of G-codes, all of which are reflect specific ICF terminology:

- Impairments of Body Functions and/or Impairments of Body Structures;
- Activity Limitations and Participation Restrictions; and
- Environmental Factors Barriers.

Each pair contained a G-code to represent the beneficiary's current functional status and another G-code to represent the beneficiary's projected goal status. Like the G-codes in this proposal, these G-codes would have been used with modifiers to reflect the severity/complexity of each element.

This set of G-codes appeared to us to be potentially redundant and confusing since we are using the term functional limitations to be synonymous with the ICF terminology "activity limitations and participation restrictions." Requiring separate reporting on three elements would have imposed a burden on therapists without providing a meaningful benefit in the value of the data provided. Further, because environmental barriers as discussed in CY 2011 are contextual, we do not believe collecting information on them would contribute to developing an improved payment system or assist with medical review. Since our goal is to develop a system that imposes the minimal additional burden while providing adequate data to accomplish the statutory directive (to assist in reforming the Medicare payment system for outpatient therapy services), we are proposing to require that just one set of G-codes be used for reporting the primary functional limitation. We added a second set of G-codes for a secondary functional limitation, which are identical to those used for the primary functional limitation. We are interested in public comment on the whether these proposed G-codes allow adequate reporting on beneficiary's functional limitations. We would particularly appreciate receiving specific suggestions for any missing elements.

(3) Severity/Complexity Modifiers

For each functional G-code used on a claim, a modifier would be required to report the severity/complexity for that functional limitation. We propose to adopt a 12-point scale to report the severity or complexity of the functional limitation involved. The proposed modifiers are listed in Table 18.

**TABLE 18: Proposed Modifiers**

| Modifier | Impairment Limitation Restriction Difficulty |
|---|---|
| XA | 0% |
| XB | Between 1-9% |
| XC | Between 10 - 19% |
| XD | Between 20 - 29% |
| XE | Between 30 - 39% |
| XF | Between 40 - 49% |
| XG | Between 50 - 59% |
| XH | Between 60 - 69% |
| XI | Between 70 - 79% |
| XJ | Between 80 - 89% |
| XK | Between 90 - 99% |
| XL | 100% |

An example of how a therapist would translate data from another assessment tool to this scale may be helpful. In our example, the physical therapist used the Berg Balance Scale (the long original version) to document the beneficiary's functional balance restriction and the beneficiary's test score is 33. (The scores on this test range from 0 – 56. A score below 41 is considered to be at moderate risk of falling.) Once the test is completed, the therapist maps the beneficiary's score to our severity modifier scale. To do so, the beneficiary's score must first be converted to a percentage. A score of 33 on a scale of 56 would equal 59 percent. To map the percentage from the Berg Balance Scale to the modifier scale, it must be subtracted from 100, since zero on the Berg Balance Scale reflects 100 percent limitation/disability. When 59 percent is subtracted from 100 percent, the result is 41 percent. This number falling between 40 percent and 49 percent is mapped to the severity modifier of "XF."

As already noted, there are many other valid and reliable measurement tools that therapists use to quantify functional limitations. Among these are four assessment tools we discussed in CY 2011 PFS rulemaking – namely, the Activity Measure – Post Acute Care (AM-PAC) tool, the FOTO Patient Inquiry, OPTIMAL, and NOMS. We list these tools as

recommended for use by therapists, though not required, in the outpatient therapy IOM provision of the Benefits Policy Manual, Chapter 15, Section 220.3C "Documentation Requirements for Therapy Services." The scores from these and other measurement tools already in use by therapy disciplines produce numerical or percentage scores that can be mapped or crosswalked to the proposed severity modifier scale. The advantage of using an assessment tool that yields a composite score, such as NOMS, would be that only the G-codes for the primary functional limitation would need to be reported even if we required reporting of secondary limitations.

In assessing the ability of therapists to provide the required severity information regardless of what assessment tool they use, if any, we considered the comments received on the CY 2011 PFS proposed rule discussion and our preliminary experience from the DOTPA project. Both indicated that we needed greater granularity in our severity scale to more accurately assess changes in functional limitation over the course of therapy. Specifically, most commenters favored the 7-point scale over the 5-point ICF-based scale. They preferred a scale with more severity levels since it would allow the therapist to document smaller changes that many therapy beneficiaries make towards their goals. For example, the "severe" level of the 5-point scale includes a 45-point spread (from 50 - 95 percent) making it difficult to document a change or improvement in a beneficiary's condition whose limitation being rated falls into this category. Commenters also liked the equal increments of the 7-point scale.

We believe that neither the five- or seven-point scales are adequate for this reporting system, and developed a new scale. The 12-point scale we are proposing is an enhancement of the 7-point scale. It achieves the ability to more accurately capture changes in functional limitations over the course of treatment and is easier to use and understand. It addresses the concern of a major association, which supported the 7-point scale, but suggested that an even more sensitive rating scale (one with more increments) might be necessary to show progress of

certain beneficiaries toward their projected goals, particularly those beneficiaries with neurological conditions, such as strokes. In addition, the proposed scale's 10-percentage point increments make it easier for therapists to convert composite and overall scores from assessment instruments or other measurement tools to this scale.

(4) Adaptation for G-Codes by Select Categories of Functional Limitations

The ultimate goal of gathering information on beneficiary function is to have adequate information to develop an alternative payment system for therapy services. Although the information that would be collected pursuant to the proposal discussed above would greatly increase our understanding of the therapy services furnished and any progress made as a result of these services, it would leave us far short of the data needed for developing a new payment system. A significant limitation of this proposal is that it would not provide data by type of functional limitation involved. We have been unable to identify an existing system that categorizes the variety of functional limitations addressed by therapists. Without an existing system that could be used to collect data on specific functional limitations, we could not develop and implement a complete system categorizing all functional limitations within the time period allowed by the statute.

However, we could begin to collect data on select categories of functional limitations by adapting the reporting system described above to include some category specific-reporting in addition to the generic reporting. Should we decide to use a system with category-specific reporting, we would expect to develop specific nonpayable G-codes for select categories of functional limitations in the final rule. Under this adaptation, if one of the select categories of functional limitations created describes the functional limitation being reported, that G-code set would be used to report the current, projected goal, and discharge status of the beneficiary. Any functional limitation not identified in this limited G-code set would be reported using the

generic G-codes previously described.

To demonstrate this approach, we have created G-codes that describe the two most frequently reported functional limitations by each of the three therapy disciplines in the DOTPA project. (See Table 19.) When appropriate, these G-codes would be used exactly as the generic ones.

**TABLE 19: Select Categories of G-Codes**

| | |
|---|---|
| Walking & Moving Around | |
| Walking & moving around functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals | GXXX8 |
| Walking & moving around functional limitation, projected goal status, at initial therapy treatment/outset and at discharge from therapy | GXXX9 |
| Walking & moving around functional limitation, discharge status, at discharge from therapy/end of reporting on limitation | GXX10 |
| Changing & Maintaining Body Position | |
| Changing & maintaining body position functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals | GXX11 |
| Changing & maintaining body position functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy | GXX12 |
| Changing & maintaining body position functional limitation, discharge status at discharge from therapy/end of reporting on limitation | GXX13 |
| Carrying, Moving & Handling Objects | |
| Carrying, moving & handling objects functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals | GXX14 |
| Carrying, moving & handling objects functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy | GXX15 |
| Carrying, moving & handling objects functional limitation, discharge status at discharge from therapy/end of reporting on limitation | GXX16 |
| Self Care (washing oneself, toileting, dressing, eating, drinking) | |
| Self care functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals | GXX17 |
| Self care functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy | GXX18 |
| Self care functional limitation, discharge status at discharge from therapy/end of reporting on limitation | GXX19 |
| Communication: Reception (spoken, nonverbal, sign language, written) | |
| Communication: Reception functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals | GXX20 |
| Communication: Reception functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy | GXX21 |
| Communication: Reception functional limitation, discharge status at discharge from therapy/end of reporting on limitation | GXX22 |
| Communication: Expression (speaking, nonverbal, sign language, writing) | |

| | |
|---|---|
| Communication: Expression functional limitation, current status at time of initial therapy treatment/episode outset and reporting intervals | GXX23 |
| Communication: Expression functional limitation, projected goal status at initial therapy treatment/outset and at discharge from therapy | GXX24 |
| Communication: Expression functional limitation, discharge status at discharge from therapy/end of reporting on limitation | GXX25 |

The benefit of having these select G-code sets in addition to the general G-codes is that the data collected could be analyzed by specific diagnoses/conditions and categories of functional limitations. We believe that in order to develop an improved payment system for therapy services this type of information is needed. Moreover, expansion of these categorical G-codes to encompass many more categories of functional limitations is essential. However, implementing specific G-codes for a select set of functional limitations could be a starting point. An initial data set could allow us to begin collecting the necessary data. It would also help us to evaluate how such a system works and make improvements before imposing requirements across the board.

We seek input from therapists on categories of functional limitations, such as those described in this section. We specifically request comments regarding the following questions. Would data collected on categories of functional limitations provide more meaningful data on therapy services than that collected through use of the generic G-codes in our proposal? Should we choose to implement a system that is based on at least some select categories of functional limitation, which functional limitations should we collect data on in 2013? Is it more, less or the same burden to report on categories of functional limitations or generic ones? The categories of functional limitations described above are based on the ICF categories, but these ICF categories also have subcategories. Should we use subcategories for reporting? Are there specific conditions not covered by these ICF categories? Would we need to have G-codes for the same categories of secondary limitations?

(5) Reporting Frequency

We propose to require this claims-based reporting in conjunction with the initial service at the outset of a therapy episode, at established intervals during treatment and at discharge. The number of G-codes required on a particular claim would vary from one to four, depending on the circumstances. Table 20 shows a graphic example of which codes are used for specified reporting. We would note that the example represents a therapy episode of care occurring over an extended time period. This example might be typical for a beneficiary receiving therapy for the late effects of a stroke. We chose to use an example with a much higher than average number of treatment days in order to show a greater variety of reporting scenarios.

**TABLE 20: Example**

| | Evaluation/Treatment Day 1 Begin Reporting Period #1 | End Reporting Period #1 | Begin Reporting Period #2 | Claim for treatment days 5 and 6 in Period #2 | End Reporting Period #2 | Begin Reporting Period #3 | Discharge /End of reporting on Primary Functional Limitation | End Reporting Period #3 |
|---|---|---|---|---|---|---|---|---|
| Primary Function Status | | | | | | | | |
| GXXX1 – Current | X | X | X | | X | X | | |
| GXXX2 – Goal | X | | X | | | X | X | |
| GXXX3 – Discharge | | | | | | | X | |
| Secondary Function | | | | | | | | |
| GXXX4 – Current | | | X | | X | X | | X |
| GXXX5 – Goal | | | X | | | X | | |
| GXXX6 – Discharge | | | | | | | | |
| No Functional Reporting Required | | | | | | | | |
| GXXXX7 | | | | X | | | | |

● Outset. Under this proposal, the first reporting of G-codes and modifiers would occur when the outpatient therapy episode of care begins. This would typically be the date of service when the therapist furnishes the evaluation and develops the required plan of care for the beneficiary. At the outset, the therapist would use the G-codes and modifiers to report a current

status and a projected goal for the primary functional limitation. If a secondary functional limitation needs to be reported at this time, the same information would be reported using G-codes and associated modifiers for the secondary functional limitation.

- Every 10 Treatment Days or 30 Calendar Days, Whichever Is Less. We propose to require that the reporting frequency for G-codes and associated modifiers be once every 10 treatment days or at least once during each 30 calendar days, whichever time period is shorter. The first treatment day for purposes of reporting would be the day that the initial visit takes place. The date the episode of care begins, typically at the evaluation, even when the therapist does not furnish a separately billable procedure in addition to the evaluation for this day, would be considered treatment day one, effectively beginning the count of treatment days or calendar days for the first reporting period.

In calculating the 10 treatment days, a treatment day is defined as a calendar day in which treatment occurs resulting in a billable service. Often a treatment day and a therapy "session" or "visit" may be the same, but the two terms are not interchangeable. Infrequently, for example, a beneficiary might receive certain services twice a day – these two different sessions (or visits) in the same day are counted as one treatment day).

On the claim for service on the 10$^{th}$ treatment day or the 30$^{th}$ calendar day after treatment day one, the therapist would only report GXXX1 and the appropriate modifier to show the beneficiary's functional status at the end of this reporting period. If also reporting on a secondary functional limitation, GXXX4 and the appropriate modifier would be included as well.

The next reporting period begins on the next treatment day, that is, the time period between the end of one reporting period and the next treatment day does not count towards the 30 calendar day period. On the claim for services furnished on this date, the therapist would report both the G-code and modifier showing the current functional status at this time along with

the G-code and modifier reflecting the projected goal that was identified at the outset of the therapy episode. This process would continue until the beneficiary concludes the course of therapy treatment.

On a claim for a service that does not require specific reporting of a G-code with modifier (that is, a claim for services between the first and the tenth day of service and that is less than 30 days from the initial assessment), GXXX7 would be used. By using this code, the therapist would be confirming that the claim does not require specific functional limitation reporting. This is the only G-code that is reported without a severity modifier.

The count of days, both treatment and calendar, for the second reporting period and any others thereafter, would begin on the first treatment day after the end of the previous reporting period.

We selected the 10/30 frequency of reporting to be consistent with our timing requirements for progress reports. These timing requirements are included in the Documentation Requirements for Therapy Services (see Pub. 100-02, Chapter 15, Section 220.3, Subsection D). By making these reporting timeframes consistent with Medicare's other requirements, therapists, who are already furnishing therapy services to Medicare outpatients, would have a familiar framework for successfully adopting our new reporting requirement. This should minimize the additional burden. In addition to reflecting the Medicare required documentation for progress reports, we believe that this simplifies the process and minimizes the new burden on practitioners since many therapy episodes would be completed by the 10th treatment day. In 2008, the average number of days in a therapy episode was nine treatment days for SLP, 11 treatment days for PT, and 12 treatment days for OT. When reporting on two functional limitations, the therapist would report the G-codes and modifiers for the second condition in the manner described above. In other words, at the end of the reporting period, two G-codes would be reported to show current

functional status – one for the primary (GXXX1) and one for the secondary (GXXX4) limitation. Similarly, at the beginning of the reporting period four G-codes would be reported. GXXX1 and GXXX4 would be used to report current status for the primary and secondary functional limitations, respectively; and, GXXX2 and GXXX5 would be used to report the goal status for the primary and secondary functional limitations, respectively.

The reporting periods must be the same for both the primary and secondary functional limitation. The therapist can accomplish this by starting them at the same time or if the secondary functional limitation is added at some point in treatment, the primary functional limitation's reporting period must be re-started by reporting GXXX1 and GXXX2 at the same time the new secondary functional limitation is added using GXXX4 and GXXX5.

Further, for those therapy treatment episodes lasting longer periods of time, the periodic reporting of the G-codes and associated modifiers would reflect any progress that the beneficiary made toward the identified goal. In summary, we propose to require the reporting of G-codes and modifiers at episode outset (evaluation or initial visit), and once every 10th treatment day or at least every 30 calendar days, whichever time period is less.

We believe it is important that the requirements for this reporting system be consistent with the requirements for documenting any progress in the medical record as specified in our manual. Given the current proposal for claims-based data collection, we believe it is an appropriate time to reassess the manual requirements. Toward this vein, we are seeking comment on whether it would be appropriate to modify the progress note requirement in the IOM to one based solely on the number of treatment days, such as six or ten. Should this modification be made, a corresponding change would be made in the reporting periods. We seek comments regarding clinical impact of such a change.

- Discharge. In addition, we are proposing to require reporting of the G-code/modifier

functional data at the conclusion of treatment so that we have a complete set of data for the therapy episode of care. Requiring the reporting at discharge mirrors the IOM requirement of a discharge note or summary. This set of data would reveal any functional progress or improvement the beneficiary made toward the projected therapy goal during the entire therapy episode. Specifically, having information on the beneficiary's functional status at the time of discharge shows whether or to what degree the projected therapy goal was met.

To report the current status of the functional limitation at the time of discharge, the therapist would use GXXX3 and the appropriate modifier. Where there is a secondary functional limitation, GXXX6, along with its appropriate modifier, would also be reported. In addition, GXXX2, along with the modifier established at the outset of therapy, is used to report the projected goal status of the primary functional limitation. And, GXXX4 and its corresponding modifier is reported to show the projected goal status for the secondary functional limitation that was established at the outset of therapy. The imposition of this reporting requirement does not justify scheduling an additional, and perhaps medically unnecessary, final session in order to measure the beneficiary's function for the sole purpose of reporting.

Although collection of discharge data is important in achieving our goals, we recognize that data on functional status at the time therapy concludes is likely to be incomplete for some beneficiaries receiving outpatient therapy services. The DOTPA project has found this to be true. There are various reasons as to why the therapist would not be able to report functional status using G-codes and modifiers at the time therapy ends. Sometimes, beneficiaries may discontinue therapy without alerting their therapist of their intention to do so, simply because they feel better, they can no longer fit therapy into their work schedules, or their transportation is unavailable. Whatever the reason, there would be situations where the therapy ends without a discharge visit. In these situations, we would not require the reporting at discharge. However,

we encourage therapists to include discharge reporting whenever possible on the final claims.

For example, since the therapist is typically reassessing the beneficiary during the therapy sessions, the data critical to the severity/complexity of the functional measure may be available even when the final therapy session does not occur. In these instances, the G-codes and modifiers appropriate to discharge should be reported.

We are particularly interested in how often the therapy community finds that beneficiaries discontinue therapy without the therapist knowing in advance that it is the last treatment session and other situations in which the discharge data would not be available for reporting.

- Significant Change in Beneficiary Condition. We are proposing that, in addition to reporting at the intervals discussed above, the G-code/modifier measures would be required to be reported when a formal and medically necessary re-evaluation of the beneficiary results in an alteration of the goals in the beneficiary's POC. This could result from new clinical findings, an added comorbidity, or a failure to respond to treatment described in the POC. This reporting affords the therapist the opportunity to explain a beneficiary's failure to progress toward the initially established goal(s) and permits either the revision of the severity status of the existing goal or the establishment of a new goal or goals. The therapist would be required to begin a new reporting period when submitting a claim containing a CPT code for an evaluation or a re-evaluation. These G-codes, along with the associated modifiers, could be used to show an increase in the severity of one or two functional limitations; or, they could be used to reflect the severity of newly identified functional limitations as delineated in the revised plan of care.

(6) Documentation

We propose to require that documentation of the information used for reporting under this system must be included in the beneficiary's medical record. The therapist would need to

track in the medical record the G-codes and the corresponding severity modifiers that were used to report the status of the functional limitations at the outset of the therapy episode, at the beginning and end of each reporting period, and at the time of discharge (or to report that the projected goal has been achieved and reporting on the particular functional limitation has ended). It is important to include this information in the record in order to create an auditable record and so that this record would also serve to improve the quality of data CMS collects as it will help the therapist keep track of assessment and treatment information for particular beneficiaries.

For example, the therapist selects the functional limitation of "walking and moving" as the primary limitation and determines that at therapy outset the beneficiary has a 60 percent limitation and sets the goal to reduce the limitation to 5 percent. The therapist uses GXXX1-XH to report the current status of the functional impairment; and GXXX2-XB to report the goal. The therapist should note in the beneficiary's medical record that the functional limitation is "walking and moving" and document the G-codes and severity modifiers used to report this functional limitation on the claim for therapy services.

(7) Claims Requirements

Except for the addition of the proposed G-codes and modifiers, nothing in this proposal would modify other existing requirements for submission of therapy claims. For example, the therapy modifiers – GO, GP, and GN – are still required to indicate that the therapy services, for which the G-codes and modifiers are used to report function on, are furnished under a OT, PT, or SLP plan of care, respectively.

Claims from institutional providers, which are submitted to the fiscal intermediaries (FIs) and A/B MACs, would require that a charge be included on the service line for each one of these G-codes in the series, GXXX1 - GXXX7. This charge would not be used for payment purposes and would not affect processing. Claims for professional services submitted to carriers and A/B

MACs do not require that a charge be included for these nonpayable G-codes but reporting a charge for the nonpayable G-codes would not affect claims processing.

Medicare does not process claims that do not include a billable service. As a result, reporting under this system would need to be included on the same claim as a furnished service that Medicare covers.

(8) Implementation Date

In accordance with section 3005(g) of the MCTRJCA, we propose to implement these data reporting requirements on January 1, 2013. We recognize that with electronic health records and electronic claims submission, therapists may encounter difficulty in including this new data on claims. To accommodate those that may experience operational or other difficulties with moving to this new reporting system and to assure smooth transition, we are proposing a testing period from January 1, 2013 until July 1, 2013. We would expect that all those billing for outpatient therapy services would take advantage of this testing period and begin attempting to report the new G-codes and modifiers as quickly as possible on or after January 1, 2013, in preparation for required reporting beginning on July 1, 2013. Taking advantage of this testing period would help to minimize potential problems after July 1, 2013, when claims without the appropriate G-codes and modifiers would be returned unpaid.

(9) Compliance Required as a Condition for Payment and Regulatory Changes

To implement the reporting system required by MCTRJCA and described above we are proposing to amend the regulations establishing the conditions for payment governing PT, OT, SLP, and CORFs to add a requirement that the claims include information on beneficiary functional limitations. In addition, we propose to amend the plan of care requirements set forth in the regulations for outpatient therapy services and CORFs to require that the therapy goals, which must be included in the POC, are consistent with the beneficiary function reporting on

claims for services.

Specifically, we propose to amend the regulations for outpatient OT, PT, and SLP (§410.59, §410.60, and §410.62, respectively) by adding a new paragraph (a)(4) to require that claims submitted for furnished services contain the information on beneficiary functional limitations as described in this rule.

We also propose to amend the plan of care requirements set forth at §410.61(c) to require that the therapy goals, which must be included in the treatment plan, must be consistent with those reported on claims for services. This requirement is in addition to those already existing conditions for the POC

To achieve consistency in the provision of PT, OT, and SLP services across settings, we propose to amend §410.105 to include the same requirements for these services furnished in CORFs. These proposed revisions would require that the goals in the treatment plan be consistent with the beneficiary function reported on claims for services and that claims submitted for furnished services contain specified information on beneficiary functional limitations, respectively. Respiratory therapy services furnished in CORFs are not subject to the reporting requirements, and therefore, these requirements would not apply to them.

(10) Consulting with Relevant Stakeholders

Section 3005(g) of the MCTRJCA requires us to consult with relevant stakeholders as we propose and implement this reporting system. We are meeting this requirement through the publication of this proposal, and specifically solicit public comment on the various aspects of our proposals. In addition, we plan to meet with key stakeholders and will discuss this issue in Open Door Forums over the course of the summer.

H. Primary Care and Care Coordination

In recent years, we have recognized primary care and care coordination as critical components in achieving better care for individuals, better health for individuals, and reduced expenditure growth. Accordingly, we have prioritized the development and implementation of a series of initiatives designed to ensure accurate payment for, and encourage long-term investment in, primary care and 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 **Federal Register** on November 2, 2011 (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) website at http://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 Innovation Center's website at http://innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html).

● The Primary Care Incentive Payment (PCIP) Program (described on the CMS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf).

● The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available. (described on the CMS Website at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf). The goal of the

MAPCP demonstration is to take a multi-payer approach to creating more advanced primary care services or "medical homes" that utilize a team approach to care, while emphasizing prevention, health information technology, care coordination, and shared decision making. CMS will pay a monthly care management fee for Medicare fee-for-service beneficiaries receiving primary care from advanced primary care practices participating in the demonstration. The following states are participating in the MAPCP demonstration: Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota. [1]

● The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS Website at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf and Innovation Center's website at http://innovations.cms.gov/initiatives/FQHCs/index.html). Participating FQHCs in the demonstration are expected to achieve National Committee for Quality Assurance (NCQA) Level 3 Patient-Centered Medical Home recognition by the end of the demonstration as well as help patients manage chronic conditions and actively coordinate care for patients. To help participating FQHCs make the needed investments in patient care and infrastructure, CMS is paying a monthly care management fee for each eligible Medicare fee-for-service beneficiary receiving primary care services. In addition, both CMS and the Health Resources Services Administration (HRSA) are providing technical assistance to FQHCs participating in the demonstration.

● The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's website at http://innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in the following

[1] More information about the MAPCP demonstration is available at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1230016.html.

markets: Arkansas, Colorado, New Jersey, New York in the Capital-District-Hudson Valley Region, Ohio and Kentucky in the Cincinnati-Dayton Region, Oklahoma in the Greater Tulsa Region, and Oregon. CMS pays a monthly care management fee to selected primary care practices on behalf of their fee-for-service Medicare beneficiaries and in years 2-4 of the initiative, each practice has the potential to share in savings to the Medicare program.

In coordination with these initiatives, we also continue to explore other potential refinements to the PFS that would appropriately value primary care and care coordination within Medicare's statutory structure for fee-for-service physician payment and quality reporting. We believe that improvements in payment for primary care and recognizing care coordination initiatives are particularly important as EHR technology diffuses and improves the ability of physicians and other providers of health care to work together to improve patient care. We view these potential refinements to the PFS 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.

The annual PFS notice and comment rulemaking process provides an important avenue for interested parties to provide input on discrete proposals intended to achieve these goals. Should any of these discrete proposals become final policy, we would expect many of them to be short-term payment strategies 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.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794), we initiated a discussion to gather information about how primary care services have evolved to focus on preventing and managing chronic disease. We also proposed to review evaluation and

management (E/M) services as potentially misvalued and suggested that the American Medical Association Relative (Value) Update Committee (AMA RUC) might consider changes in the practice of chronic disease management and care coordination as key reason for undertaking this review. In the CY 2012 PFS final rule with comment period, we did not finalize our proposal to review E/M codes due to consensus from an overwhelming majority of commenters that a review of E/M services using our current processes could not appropriately value the evolving practice of chronic care coordination, and therefore, would not accomplish the agency's goal of paying appropriately for primary care services. We stated that we would continue to consider ongoing research projects, demonstrations, and the numerous policy alternatives suggested by commenters. In addition, in the CY 2012 PFS proposed rule (76 FR 42917 through 42920), we initiated a public discussion regarding payments for post-discharge care management services. We sought broad public comment on how to further improve care management for a beneficiary's transition from the hospital to the community setting within the existing statutory structure for physician payment and quality reporting. We specifically discussed how post discharge care management services are coded and valued under the current E/M coding structure, and we requested public comment.

The physician community responded that comprehensive care coordination services are not adequately represented in the descriptions of, or payments for, office/outpatient E/M services. The American Medical Association (AMA) and the American Academy of Family Physicians (AAFP) created workgroups to consider new options for coding and payment for primary care services. The AAFP Task Force recommended that CMS create new primary care E/M codes and pay separately for non-face-to-face E/M Current Procedural Terminology (CPT) codes. (A summary of these recommendations is available at http://www.aafp.org/online/en/home/publications/news/news-now/inside-

aafp/20120314cmsrecommendations.html.) The AMA workgroup, Chronic Care Coordination Workgroup (C3W), is developing codes to describe care transition and care coordination activities. (Several workgroup meeting minutes and other related items are available at http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/care-coordination.page) We are continuing to monitor the progress of this workgroup and look forward to receiving its final recommendations. For this CY 2013 PFS proposed rule, we have decided to proceed with a proposal to refine PFS payment for post discharge care management services. We also include a discussion of how we could incorporate the idea of advanced primary care through practices certified as medical homes in the FFS setting. In developing the proposal and discussion described below, we have thoroughly considered documented concerns regarding Medicare payment for non-face-to-face elements of E/M services that are crucial to care coordination. We will continue to consider other enhancements to payment for primary care services and complex chronic care coordination services, and we may make further proposals to improve payment mechanisms and foster quality care for these and similar services in future rulemaking.

Under current PFS policy, care coordination is a component of E/M services which are generally reported using E/M CPT codes. 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 coordination work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include providing care coordination, communication, and other necessary care management related to the office visit in the post-service work. We also highlighted vignettes that describe a typical service for hospital

discharge day management (CPT codes 99238 and 99239), which include providing care coordination, communication, and other necessary management related to the hospitalization in the post-service work.

As we have indicated many times in prior rulemaking, the payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits. Moreover, Medicare does not pay for services that are furnished to parties other than the beneficiary and which Medicare does not cover, for example, communication with caregivers. Accordingly, we do not pay separately for CPT codes for telephone calls, medical team conferences, prolonged services without patient contact, or anticoagulation management services.

However, we continue to hear concerns from the physician community that the care coordination included in many of the E/M services, such as office visits, does not adequately describe the non-face-to-face care management work involved in primary care. 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 such as those who are returning to a community setting following discharge from a hospital or SNF stay. We are therefore considering new options to recognize the additional resources typically involved in furnishing coordinated care to particular types of beneficiaries.

As described below, we are proposing to address the significant non-face-to-face work involved in coordinating services for a beneficiary after discharge from a hospital or skilled nursing facility (SNF). Specifically, we propose to create a HCPCS G-code to describe care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay (inpatient, outpatient observation services, or outpatient partial

hospitalization), SNF stay, or community mental health center (CMHC) partial hospitalization program to care furnished by the beneficiary's primary physician in the community. We consider this proposal to be part of a multiple year strategy exploring the best means to encourage care coordination services. Furthermore, in the interest of encouraging comprehensive primary care services furnished in advanced primary care practices, we have included a discussion regarding how care furnished in these settings might be incorporated into the current fee-for-service structure of the PFS We look forward to continued development of these ideas through current research and demonstration projects, experience with ACOs and other programs, and further discourse on these issues with stakeholders.

1. Hospital, SNF, or CMHC Post-Discharge Care Management

a. Background

Care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital, SNF, or CMHC stay to the beneficiary's primary physician in the community can avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system. Successful efforts to improve hospital discharge care management and care transitions could improve the quality of care while simultaneously decreasing costs.

Currently, there are several agency initiatives aimed at hospital and community-based organizations. In April 2011, HHS launched the Partnership for Patients, a national public-private patient safety initiative for which more than 6,000 organizations—including physician and nurses' organizations, consumer groups, employers and over 3,000 hospitals—have pledged to help achieve the Partnership's goals of reducing hospital complications and improving care transitions. (More information on this initiative is available at http://innovations.cms.gov/initiatives/partnership-for-patients/index.html.) The Partnership for

Patients includes the Community-based Care Transitions Program, created by section 3026 of the Affordable Care Act, which provides funding to community-based organizations partnering with eligible hospitals to coordinate a continuum of post-acute care to test models for improving care transitions for high risk Medicare beneficiaries.

Section 1886(q) of the Act (as added by section 3025 of the Affordable Care Act) directs the Secretary to establish a Hospital Readmissions Reduction Program, beginning in FY 2013, for certain potentially preventable Medicare inpatient hospital readmissions covering three conditions: heart attack; pneumonia; and congestive heart failure. Beginning in FY 2015, the number of applicable conditions can be expanded beyond the initial three conditions. Under this program, a portion of Medicare's payment amounts for inpatient services to certain hospitals will be reduced by an adjustment factor based the hospital's excess Medicare readmissions. In the FY 2012 IPPS final rule (76 FR 51662-51676), we provided an overview of the Hospital Readmission Reduction program and finalized policies regarding selection of applicable conditions, definition of "readmissions," measures of the applicable conditions chosen for readmissions, methodology for calculating the excess readmissions ratio, public reporting of readmission data, and definition of applicable period. In the FY2013 IPPS proposed rule (77 FR 27955-27968), we made proposals regarding the base operating DRG payment amount, the adjustment factor, aggregate payments for excess readmissions, and the hospitals that would be included in the program.

In its 2007 Report to Congress: Promoting Greater Efficiency in Medicare, MedPAC found that, in 2005, 17.6 percent of admissions resulted in readmissions within 30 days of discharge, accounting for $15 billion in spending. MedPAC estimated that 76 percent of the 30 day readmissions were potentially preventable, resulting in $12 billion in spending. In the same report, MedPAC also found that the rate of potentially avoidable rehospitalizations after

discharges from skilled nursing facilities was 17.5 percent in 2004 (an increase of 2.8 percentage points from 2000.) MedPAC noted: "We focus on the hospital's role but recognize that other types of providers, including physicians and various post-acute care providers, can be instrumental in avoiding readmissions…[C]ommunity physicians and post-acute care providers receiving the patient may not be sufficiently informed about the patient's care needs and history to enable effective care." We agree with MedPAC that primary care physicians and practitioners play a key role in post-acute care and reducing hospital readmissions.

In the CY 2012 PFS proposed rule (76 FR 42917 through 42920), we initiated a public discussion regarding payments for post-discharge care coordination services. We sought broad public comment on how to further improve physician care coordination within the statutory structure for physician payment and quality reporting, particularly for a beneficiary's transition from the hospital to the community. As noted above, we also proposed to review E/M services as potentially misvalued and suggested that the AMA RUC might consider chronic disease management and care coordination in its review (76 FR 42793). While the commenters agreed that care coordination would lead to better care for beneficiaries, they believed this care would be better described by new codes, and not the current E/M codes.

b. Hospital and SNF Discharge Services

We believe that the successful transition of a beneficiary from care furnished by a hospitalist physician to care furnished by the beneficiary's primary physician or qualified nonphysician practitioner could avoid adverse events such as readmissions or subsequent illnesses, improve beneficiary outcomes, and avoid a financial burden on the health care system.

We also believe that the current hospital discharge management codes (CPT codes 99238 and 99239) and nursing facility discharge services (CPT codes 99315 and 99316) adequately capture the care coordination services required to discharge a beneficiary from hospital or skilled

nursing facility care. The work relative values for those discharge management services include a number of pre-, post-, and intra-care coordination activities. For example, the hospital discharge management codes include the following pre-, intra-, and post- service activities relating to care coordination:

Pre-service care coordination activities include:

- Communicate with other professionals and with patient or patient's family.

Intra-service care coordination activities include:

- Discuss aftercare treatment with the patient, family and other healthcare professionals;
- Provide care coordination for the transition including instructions for aftercare to caregivers;
- Order/arrange for post discharge follow-up professional services and testing; and
- Inform the primary care or referring physician or qualified nonphysician practitioner of discharge plans.

Post-service care coordination activities include:

- Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this hospitalization; and
- Revise treatment plan(s) and communicate with patient and/or caregiver, as necessary.

The hospital and nursing facility discharge management codes also include a number of other pre-, intra and post-service activities.

Because these activities are critical to successfully avoiding readmissions, we seek comment about the best ways to ensure that all the activities of the discharge day management codes for hospital and nursing facility discharge, including the care coordination activities, are understood and furnished by the physicians or qualified nonphysician practitioners who bill for these services. Potential ways could include physician education or MEDLEARN articles.

c. Defining Post-Discharge Transitional Care Management Services

While we believe that current hospital and nursing facility discharge management service codes adequately capture the care management activities involved with discharging a beneficiary from a hospital or skilled nursing facility, we do not believe that current E/M office or other outpatient visit CPT codes appropriately describe comparable care management work of the community physician or qualified nonphysician practitioner coordinating care for the beneficiary post-discharge. This is because the E/M codes represent the typical outpatient office visit and do not capture or reflect the significant care coordination activities that need to occur when a patient transitions from institutional to community-based care. We believe that the work of the discharging physician or qualified nonphysician practitioner should be complemented by corresponding work of a receiving physician or qualified nonphysician practitioner in the community in order to ensure better continuity of care through establishing or revising a plan of care for the beneficiary after discharge. We acknowledge that many, if not most, physicians or qualified nonphysician practitioners caring for beneficiaries following a hospital or nursing facility discharge have been furnishing coordinated care and reporting office or other outpatient CPT codes. However, we agree with commenters to the CY 2012 proposed and final rules that the services described by current E/M office or other outpatient CPT codes 99201 through 99215 may not appropriately capture the significant coordination services involved in post-discharge care.

We are proposing to create a HCPCS G-code that specifically describes post-discharge transitional care management services. The code would describe all non-face-to-face services related to the transitional care management furnished by the community physician or qualified nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing

facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services; and a partial hospitalization program at a CMHC to community-based care. The post-discharge transitional care management service includes non-face-to-face care management services furnished by clinical staff member(s) or office-based case manager(s) under the supervision of the community physician or qualified nonphysician practitioner. We use the term community physician and practitioner in this discussion to refer to the community-based physician managing and coordinating a beneficiary's care in the post-discharge period. We anticipate that most community physicians will be primary care physicians and practitioners. We have based the concept of this proposal, in part, on our policy for care plan oversight services. We currently pay physicians for the non face-to-face care plan oversight services furnished for patients under care of home health agencies or hospices. These patients require 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. Physicians providing these services bill HCPCS codes G0181 (Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more), or G0182 (Physician supervision of a patient under a Medicare-approved hospice (patient not present) requiring complex and

multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more). (See the Medicare benefit manual, 100-02, Chapter 15,Section 30 for detailed description of these services.)

For CY 2013, we are proposing to create a new code to describe post-discharge transitional care management. This service would include:

● Assuming responsibility for the beneficiary's care without a gap.

++ Obtaining and reviewing the discharge summary.

++ Reviewing diagnostic tests and treatments.

++ Updating of the patient's medical record based on a discharge summary to incorporate changes in health conditions and on-going treatments related to the hospital or nursing home stay within 14 business days of the discharge.

● Establishing or adjusting a plan of care to reflect required and indicated elements, particularly in light of the services furnished during the stay at the specified facility and to reflect result of communication with beneficiary.

++ An assessment of the patient's health status, medical needs, functional status, pain control, and psychosocial needs following the discharge.

● Communication (direct contact, telephone, electronic) with the beneficiary and/or caregiver, including education of patient and/or caregiver within 2 business days of discharge based on a review of the discharge summary and other available information such as diagnostic test results, including each of the following tasks:

++ An assessment of the patient's or caregiver's understanding of the medication

regimen as well as education to reconcile the medication regimen differences between the pre- and post-hospital, CMHC, or SNF stay.

++ Education of the patient or caregiver regarding the on-going care plan and the potential complications that should be anticipated and how they should be addressed if they arise.

++ Assessment of the need for and assistance in establishing or re-establishing necessary home and community based resources.

++ Addressing the patient's medical and psychosocial issues, and medication reconciliation and management.

When indicated for a specific patient, the post-discharge transitional care service would also include:

- Communication with other health care professionals who will (re)assume care of the beneficiary, education of patient, family, guardian, and/or caregiver.
- Assessment of the need for and assistance in coordinating follow up visits with health care providers and other necessary services in the community.
- Establishment or reestablishment of needed community resources.
- Assistance in scheduling any required follow-up with community providers and services.

The post-discharge transitional care services HCPCS G-code we are proposing would be used by the community physician or qualified nonphysician practitioner to report the services furnished in the community to ensure the coordination and continuity of care for patients discharged from a hospital (inpatient stay, outpatient observation, or outpatient partial hospitalization), SNF stay, or CMHC. The post-discharge transitional care service would parallel the discharge day management service for the community physician or qualified

nonphysician practitioner and complement the E/M office/outpatient visit CPT codes.

The post-discharge transitional care service would support the patient's physical and psychosocial health. In our recent Decision Memorandum for Screening for Depression in Adults, CAG-00425N, we noted that depression in older adults occurs in a complex psychosocial and medical context and that, currently, we believe opportunities are missed to improve mental health and general medical outcomes when mental illness is under-recognized and undertreated in primary care settings. We wish to emphasize the equal importance of the patient's mental health to the patient's physical condition to successful re-entry into the community.

We propose that the post-discharge transitional care service HCPCS G-code would be used to report physician or qualifying nonphysician practitioner services for a patient who's medical and/or psychosocial problems require moderate or high complexity medical decision making during transitions in care from hospital (inpatient stay, outpatient observation, and partial hospitalization), SNF stay, or CMHC settings to community-based care. Moderate and high complexity medical decision making are defined in the Evaluation and Management Guidelines. In general, moderate complexity medical decision-making includes multiple diagnoses or management options, moderate complexity and amount of data to be review, a moderate amount and/or complexity of data to be reviewed; and a moderate risk of significant complications, morbidity, and/or mortality. High complexity decision-making includes an extensive number of diagnoses or management options, an extensive amount and/or complexity of data to be reviewed, and high risk of significant complications, morbidity, and/or mortality (See Evaluation and Management Services Guide, Centers for Medicare & Medicaid Services, December 2010.) We propose that the post-discharge transitional care HCPCS code (GXXX1) would be payable only once in the 30 days following a discharge, per patient per discharge, to a single community physician or qualified nonphysician practitioner (or group practice) who assumes responsibility

for the patient's post-discharge transitional care management. The service would be billable only at 30 days post discharge or thereafter. The post-discharge transitional care management service would be distinct from services furnished by the discharging physician or qualified nonphysician practitioner reporting CPT codes 99238 (Hospital discharge day management, 30 minutes or less); 99239 (Hospital discharge day management, more than 30 minutes) ; 99217 (Observation care discharge day management); or Observation or Inpatient Care services, CPT codes 99234 -99236; as appropriate.

We propose to pay the first claim that we receive for the beneficiary at 30 days after discharge. Given the elements of the service and the short window of time following a discharge during which a physician or qualifying nonphysician practitioner will need to perform several tasks on behalf of a beneficiary, we believe it is unlikely that two or more physicians or practitioners would have had a face-to-face E/M contact with the beneficiary in the specified window of 30 days prior or14 days post discharge and have furnished the proposed post-discharge transitional care management services listed above. Therefore, we do not believe it is necessary to take further steps to identify a beneficiary's community physician or qualified nonphysician practitioner who furnishes the post-discharge transitional care management services. We propose to pay only one claim for the post-discharge transitional care GXXX1 billed per beneficiary at the conclusion of the 30 day post-discharge period. Post-discharge transitional care management relating to any subsequent discharges for a beneficiary in the same 30-day period would be included in the single payment. Practitioners billing this post-discharge transitional care code accept responsibility for managing and coordinating the beneficiary's care over the first 30 days after discharge. Although we currently envision billing happening as it does for most services, after the conclusion of the service, we welcome comment on whether in this case there would be merit to allowing billing for the code to occur at the time the plan of

care is established.

We have explicitly constructed this proposal as a payment for non face-to-face post-discharge transitional care management services separate from payment for E/M or other medical visits. However, we believe that it is important to ensure that the community physician or qualified nonphysician practitioner furnishing post-discharge transitional care management either have or establish a relationship with the patient. As such, we propose that the community physician or qualified nonphysician practitioner reporting post-discharge transitional care management GXXX1 should already have a relationship with the beneficiary, or establish one soon after discharge, prior to furnishing transitional care management and billing this code. Therefore, we propose that the community physician or qualified nonphysician practitioner reporting a transitional care management HCPCS G-code must have billed an E/M visit for that patient within 30 days prior to the hospital discharge (the start of post-discharge transitional care management period), or must conduct an E/M office/outpatient visit (99201 to 99215) within the first 14 days of the 30-day post-discharge period of transitional care management services. The E/M visit would be separately billed.

While we are proposing that the post-discharge transitional care management code would not include a face-to-face visit, and that physicians or qualified nonphysician practitioners would bill and be paid for this care management service separately from a medical visit, we are seeking comments about whether we should require a face-to-face visit when billing for the post-discharge transitional care management service. We are also seeking comments regarding how we might incorporate such a required visit on the same day into the payment for the proposed code. We considered several reasons for requiring a face-to-face visit on the same day. We wondered whether, with a face-to-face visit immediately after discharge, the plan of care would be more accurate given that the patient's medical or psychosocial condition may have changed

from the time the practitioner last met with the patient and the practitioner could better develop a plan of care through an in-person visit and discussion. We also wondered whether beneficiaries would understand their coinsurance liability for the post-discharge transitional care service when they did not visit the physician's or qualified nonphysician practitioner's office. On the other hand, we have contemplated several scenarios where it is not possible for a beneficiary to get to the physician's or qualified nonphysician practitioner's office and welcome comment on whether an exception process would be appropriate if we were to finalize a same day face-to-face visit as a requirement for billing the post-discharge transitional care management code.

The proposed post-discharge transitional care HCPCS G-code would be described as follows:

**GXXX1** **Post-discharge transitional care management** with the following required elements:

- Communication (direct contact, telephone, electronic) with the patient or caregiver within 2 business days of discharge.
- Medical decision making of moderate or high complexity during the service period.
- To be eligible to bill the service, physicians or qualified nonphysician practitioners must have had a face-to-face E/M visit with the patient in the 30 days prior to the transition in care or within 14 business days following the transition in care.

We contemplated establishing a requirement that post-discharge transitional care management be furnished by a physician or qualified nonphysician practitioner or other clinical staff in the practice who are qualified to assist beneficiaries in managing post-transition changes in conditions and treatments. We welcome public comment on whether this would be an appropriate requirement for GXXX1.

We propose that a physician or qualified nonphysician practitioner who bills for

discharge management during the time period covered by the transitional care management services code may not also bill for HCPCS code GXXX1. The CPT discharge management codes are 99217, 99234-99236, 99238-99239, 99281-99285, or 99315-99316, home health care plan oversight services (HCPCS code G0181), or hospice care plan oversight services (HCPCS code G0182) . We believe these codes describe care management services for which Medicare makes separate payment and should not be billed in conjunction with GXXX1, which is a comprehensive post-discharge transitional care management service. Further, we propose that a physician or qualified nonphysician practitioner billing for a procedure with a 10- or 90-day global period would not also bill HCPCS code GXXX1 in conjunction with that procedure because any follow-up care management would be included in the post-operative portion of the global period. Many of the global surgical packages include discharge management codes. We believe that any physician or qualified nonphysician practitioner billing separately for the discharge management code that also is the community physician or nonphysician practitioner for the beneficiary would be paid for post-discharge transitional care management through the discharge management code.

We are making this proposal to provide a separate reporting mechanism to the community physician for these services in the context of the broader HHS and CMS multi-year strategy to recognize and support primary care and care management. Should any of these discrete proposals, like this one, become final policy, they may be short-term payment strategies 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 would also note that this proposal dovetails with our discussion under section III.J. of this proposed rule on the Value-based Payment Modifier and Physician Feedback Reporting Program which discusses hospital

admission measures and a readmission measure as outcome measures for the proposed value-based payment modifier adjustment beginning in CY 2105.

c. Proposed Payment for Post-Discharge Transitional Care Management Service

To establish a physician work relative value unit (RVU) for the proposed post-discharge transitional care management, HCPCS code GXXX1, we compared GXXX1 with CPT code 99238 (Hospital discharge day management; 30 minutes or less) (work RVU = 1.28). We recognize that, unlike CPT code 99238, HCPCS code GXXX1 is not a face-to-face visit. However, we believe that the physician time and intensity involved in post-discharge community care management is most equivalent to CPT code 99238 which, like the proposed new G-code, involves a significant number of care management services. Therefore, we are proposing a work RVU of 1.28 for HCPCS code GXXX1 for CY 2013. We also are proposing the following physician times: 8 minutes pre-evaluation; 20 minutes intra-service; and 10 minutes immediate post-service. The physician time file associated with this PFS proposed rule is available on the CMS Website in the Downloads section for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

In addition, we are proposing to crosswalk the clinical labor inputs from CPT code 99214 (Level 4 established patient office or other outpatient visit) to the post-discharge transitional care code. The proposed CY 2013 direct PE input database reflects these inputs and is available on the CMS Website under the supporting data files for the CY 2013 PFS proposed rule with comment period at http://www.cms.gov/PhysicianFeeSched/. The proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from application of this proposal.

For malpractice expense, we are proposing a malpractice crosswalk of CPT code 99214 for HCPCS code GXXX1 for CY 2013. We believe the malpractice risk factor for CPT code

99214 appropriately reflects the relative malpractice risk associated with furnishing HCPCS code GXXX1. The malpractice RVUs included in Addendum B to this proposed rule reflect the RVUs that result from the application of this proposal.

We note that as with other services paid under the PFS the 20 percent beneficiary coinsurance would apply to the post-discharge transitional care management service as would the Part B deductible.

For BN calculations, we estimated that physicians or qualified nonphysician practitioners would provide post-discharge transitional care management services for 10 million discharges in CY 2013. This number roughly considers the total number of hospital inpatient and SNF discharges, hospital outpatient observation services and partial hospitalization patients that may require with moderate to high complexity decision-making.

For purposes of the Primary Care Incentive Payment Program (PCIP), we are proposing to exclude the post discharge transitional care management services from the total allowed charges used in the denominator calculation to determine whether a physician is a primary care practitioner. Under section 1833(x) of the statute 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 73435-73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, in order 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.

We believe that the proposed transitional care management code should be treated in the same manner as those services for the purposes of PCIP because post-discharge transitional care management 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 are concerned that inclusion of the transitional care management 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. Therefore, while physicians and qualified nonphysician practitioners who furnish transitional care management 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), the allowed charges for transitional care management 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.

2. Primary Care Services Furnished in Advanced Primary Care Practices

a. Background

As we have discussed above, we are committed to considering new options and developing future proposals for payment of primary care services under the MPFS. Such options would promote comprehensive and continuous assessment, care management, and attention to preventive services that constitute effective primary care by establishing appropriate payment when physicians furnish such services. One method for ensuring that any targeted payment for primary care services would constitute a minimum level of care coordination and continuous assessment under the MPFS would be to pay physicians for services furnished in an "advanced primary care practice" that has implemented a medical home model supporting patient-specific

care. The medical home model has been the subject of extensive study in medical literature. Since 2007, the AMA, American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American Osteopathic Association (AOA), and many other physician organizations have also endorsed "Joint Principles of the Patient-Centered Medical Home." In February 2011, the AAFP, the AAP, the ACP, and AOA also published formal "Guidelines for Patient-Centered Medical Home (PCMH) Recognition and Accreditation Programs" to develop and promote the concept and practice of the PCMH. (These guidelines are available at http://www.aafp.org/online/etc/medialib/aafp_org/documents/membership/pcmh/pcmhtools/pcmhguidelines.Par.0001.File.dat/GuidelinesPCMHRecognitionAccreditationPrograms.pdf.) As we have discussed above, the Innovation Center has been conducting a several initiatives based on the medical home concept.

The medical home concept emphasizes establishing an extensive infrastructure requiring both capital investments and new staffing, along with sophisticated processes, to support continuous and coordinated care with an emphasis on prevention and early diagnosis and treatment. The literature, reports, and guidelines dealing with the medical home concept define the requisite elements or functions that constitute this infrastructure and processes in various ways. For example, the Innovation Center's CPC initiative identified a set of five "comprehensive primary care functions," which form the service delivery model being tested and the required framework for practice transformation under the CPC initiative. We believe these five "comprehensive primary care functions" provide an appropriate starting point for discussing the incorporation of the comprehensive primary care services delivered in advanced primary care practices (practices implementing a medical home model) into the MPFS:

1. Risk-stratified Care Management

One of the hallmarks of comprehensive primary care is the provision of intensive care management for high-risk, high-need, high-cost patients. Providers must provide routine, systematic assessment of all patients to identify and predict which patients need additional interventions. In consultation with their patients, they should create a plan of care to assure care that is provided is congruent with patient choices and values. Once patient needs, including social needs and functional deficits, have been identified, they should be systematically addressed. Markers of success include policies and procedures describing routine risk assessment and the presence of appropriate care plans informed by the risk assessment.

2. Access and Continuity

Health providers who know the patient should be accessible when a patient needs care. Providers must have access to patient data even when the office is closed so they can continue to participate in care decisions with their patients. Patients need access to the patient care team 24/7. Every patient is assigned to a designated provider or care team with whom they are able to get successive appointments. Markers of success include care continuity and availability of the EHR when the office is closed.

3. Planned Care for Chronic Conditions and Preventive Care

Primary care must be proactive. Practitioners must systematically assess all patients to determine his or her needs (one way would be through the annual wellness visit[2]) and provide proactive, appropriate care based on that assessment. Pharmaceutical management, including medication reconciliation and review of adherence and potential interactions, and oversight of patient self-management of medications for diabetes, anti-coagulation management or warfarin therapy, and other chronic conditions, should be a routine part of all patient assessments. Markers of success include completion of the Annual Wellness Visit and documentation of

[2] The Affordable Care Act (ACA) covered an annual wellness visit for Medicare beneficiaries through which they are to receive a personalized prevention plan. The ACA also ensured preventive services would be covered without cost if they are recommended by the US Preventive Services Taskforce and meet certain other conditions.

medication reconciliation.

4. Patient and Caregiver Engagement

Truly patient-centered care assumes the mantra "nothing about me without me." Providers should establish systems of care that include the patient in goal setting and decision making, creating opportunities for patient engagement throughout the care delivery process. Markers of success include policies and procedures designed to ensure that patient preferences are sought and incorporated into treatment decisions.

5. Coordination of Care across the Medical Neighborhood

The "medical neighborhood" is the totality of providers, related non-health services and patients in an area, and the ways in which they work together.[3] Primary care can be seen as the hub of the neighborhood and must take the lead in coordinating care. In particular, primary care providers must move towards leadership of health teams both within and outside their practice's walls. Providers must have the ability to access a single medical record shared by the whole team; the content of this record can be leveraged to manage communication and information flow in support of referrals to other clinicians, and to support safe and effective transitions from the hospital and skilled nursing facilities back to the community. The primary care practice must also include personnel who are qualified to assist patients to manage post transition changes in conditions and treatments required to support patients' health and reduce their need for readmission. Markers of success include the presence of standard processes and documents for communicating key information during care transitions or upon referral to other providers.

b. Advanced Primary Care Practices Accreditation and Infrastructure

1. Accreditation Utilizing Nationally Recognized Organizations

In the event that we were to establish an enhanced payment for primary care services

[3] "Coordinating Care in the Medical Neighborhood" White Paper. Agency for Healthcare Research and Quality, June 2011.

furnished to Medicare beneficiaries in an advanced primary care practice environment, we would need to establish a set of parameters to determine whether or not a clinical practice could be considered an advanced primary care practice (medical home). The foundation for our assessment could be whether the practice has the capacity to deliver comprehensive primary care services that mirror the five functions of the CPC initiative. However, we would need to identify explicit criteria in the form of documented processes and quantifiable practice attributes, such as the availability and capacity of electronic health records, to assess the presence of these five functions.

We could make our determination that a practice has implemented all identified functions and is, therefore, an advanced primary care practice, by recognizing one or more of the nationally available accreditation programs currently in use by major organizations that provide accreditation for advanced primary care practices, frequently credentialed as "PCMHs". Having established recognition of accreditation by one of several national accreditation organizations, we might require that a provider document through the enrollment process (PECOS) that the practice meets the definition of an Advanced Primary Care Practice to furnish comprehensive primary care services. We have identified four national models that provide accreditation for organizations wishing to become an advanced primary care practice; the Accreditation Association for Ambulatory Health, The Joint Commission, the NCQA, and the Utilization Review Accreditation Commission (URAC). While there are similarities between all four of the national models for PCMH accreditation, each model has different standards and areas of emphasis in its review and approval of organizational capacity and function as a PCMH. For instance, according to a report prepared for CMS by the Urban Institute entitled, "Patient-Centered Medical Home Recognition Tools: A Comparison of Ten Surveys' Content and Operational Details" released in March of 2012, the NCQA places a heavier emphasis on Health

IT than the other accrediting bodies in their measurement standards. This report can be viewed at the following link: http://www.urban.org/uploadedpdf/412338-patient-centered-medical-home-rec-tools.pdf.

We believe that basing our determination on accreditation as a PCMH by a national accreditation organization would offer a number of benefits, including that their accreditation tools, which review specific aspects of practice including information systems and organizational processes already are well known, widely used, and well respected. Level 3 NCQA accreditation, URAC, the Accreditation Association for Ambulatory Health and Joint Commission accreditation standards are, despite their differences, very similar to the concepts of the comprehensive primary care services, and CMS could consider accepting accreditation from any of these as documentation that a group practice is an advanced primary care practice. Other payers currently recognize PCMH accreditation by these organizations for payment. A publication from the Medical Group Management Association (MGMA) "The Patient Centered Medical Home Guidelines: A Tool to Compare National Programs" found that all four of the national accreditation programs met the guidelines set forth by the AAFP, the AAP, the ACP, and AOA in their 2011 guidelines. The MGMA report can be downloaded from the following Website: http://www.mgma.com/Books/Patient-Centered-Medical-Home-Guidelines/. However, we recognize that the cost to a practice to acquire accreditation from one of these accrediting organizations could be significant. In addition, the processes to receive accreditation as an advanced primary care practice under these guidelines can be lengthy. We also are concerned that some parts of the accreditation processes for these accrediting organizations would be considered proprietary. We believe that Medicare payment should rely whenever feasible on criteria and tools that are in the public domain. We also recognize that it could be challenging for us to address how we could rely on a set of standards from a private accrediting

body while still retaining responsibility for accreditation outcomes. It is unclear at this time how we would balance the proprietary interests of these private organizations in their accreditation models with our responsibility to establish and maintain appropriate transparency in our decision-making processes.

If we were to move forward with a process that would use the accreditation standards from a private sector organization to make determinations as to whether a practice is an advanced primary care practice, we would need to determine whether to recognize one, some, or all of the available and established accreditation models. As we stated above, because each accreditation tool has different standards and emphasizes different criteria, we are concerned that there could be consistency issues if we were to recognize accreditation from all four organizations as evidence of certification to provide advanced primary care. It would be important to ensure that any of the accreditation tool(s) we selected met the goals of our policy. We specifically invite comments regarding the processes that we should consider for application, confirmation that recognized accreditation standards are met, and notification of recognition as a PCMH if we were to recognize practices as advanced primary care practices based on accreditation as a PCMH by one or more of the national accreditation organizations.

2. CMS-Developed Advanced Primary Care Accreditation Criteria

Alternatively, we could develop our own criteria using, for example, the five functions of comprehensive primary care used in the CPC initiative and described above, to determine what constitutes advanced primary care for purposes of Medicare payment. We would then need to develop a process for determining whether specific physician practices meet the criteria for advanced primary care. This could include creating our own criteria and processes for review or could include using existing accrediting bodies to measure compliance against advanced primary care criteria determined by CMS. This would create more consistent standards for identifying

advanced primary care practices and provide greater transparency in the certification process. If CMS was able to determine the validity of an organization's application to be recognized to be an advanced primary care practice, this could reduce the cost to the physician practice for accreditation. However, practices would still need to invest in organizational process and infrastructure to meet advanced primary care criteria. Implementing an internal process to accredit practices as advanced primary care for purposes of Medicare payment could involve significant administrative cost. The amount of cost likely would depend on the rigor of the required criteria, and the amount of documentation and review required prior to approval as an advanced primary care practice.

If we established our own criteria in order to resolve the lack of standardization between the standards adopted by the various national accreditation organizations for PCMH, it is possible that the accrediting bodies would then be able to assist us in determining compliance with the CMS criteria. Depending on the nature of the criteria, the CMS criteria may cost less to implement but would likely require a practice to incur the cost for an accrediting body to review the practice's compliance. We invite public comment on the potential approaches we could use to identify advanced primary care practices for purposes of Medicare payment, including the possible use of one or more national accrediting organizations (and whether meaningful use of certified electronic health record technology should be required for such accreditation)as part of a Medicare approval process, as well as any other potential approaches to accrediting advanced primary care practices that we have not discussed here.

c. Beneficiary Attribution for Purposes of Payment

One potential issue surrounding comprehensive primary care services delivered in an advanced primary care practice is attribution of a beneficiary to an advanced primary care practice. We would not expect that there would be more than one practice functioning as an

advanced primary care practice for a beneficiary at any given time. However, in a fee-for-service environment we would need to determine which practice is currently serving as the advanced primary care practice for the beneficiary in order to ensure appropriate payment. One method of attribution could be that each beneficiary prospectively chooses an advanced primary care practice. We seek comment on how such a choice might be documented and incorporated into the fee-for-service environment. Other attribution methodologies might examine the quantity and type of E/M or other designated services furnished to that beneficiary by the practice. We welcome input on the most appropriate approach to the issue of how to best determine the practice that is functioning as the advanced primary care practice for each beneficiary. We are not considering proposals that would restrict a beneficiary's free choice of practitioners.

In summary, we believe that targeting primary care management payments to advanced primary care practices would have many merits including ensuring a basic level of care coordination and care management. We recognize that the advanced primary care model has demonstrated efficacy in improving the value of health care in several contexts, and we are exploring whether we can achieve these outcomes for the Medicare population through several demonstration projects. Careful analysis of the outcomes of these demonstration projects will inform our understanding of how this model of care affects the Medicare population and of potential PFS payment mechanisms for these services. At the same time, we also believe that there are many policy and operational issues to be considered when nationally implementing such a program within the PFS. Therefore, we generally invite broad public comment on the accreditation and attribution issues discussed above and any other aspect, including payment, of integrating an advanced primary care model in to the PFS.

I. Payment for Molecular Pathology Services

For CY 2012, the AMA CPT Editorial Panel began creating new CPT codes to replace the current codes used to bill for molecular pathology services. The new codes describe distinct molecular pathology tests and test methods. CPT divided these new molecular pathology codes into Tiers. Tier 1 codes describe common gene-specific and genomic procedures. Tier 2 codes capture reporting for less common tests and each Tier 2 code represents a group of tests that involve similar technical resources and interpretive work. For CY 2012, CPT created 101 new molecular pathology codes; 92 new Tier 1 codes for individual tests and nine Tier 2 codes for common groups of tests. These codes appear in Table 21. We anticipate that CPT will create additional molecular pathology codes for CY 2013.

We stated in our notice for the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting (to be held July 16-17, 2012 at CMS headquarters in Baltimore, Maryland, more information at https://www.cms.gov//Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Public_Meetings.html) that we are following our process to determine the appropriate basis and payment amounts for new clinical diagnostic laboratory tests, including the molecular pathology tests, under the CLFS for CY 2013. However, we also stated that we understand stakeholders in the molecular pathology community continue to debate whether Medicare should pay for molecular pathology tests under the CLFS or the PFS. Medicare pays for clinical diagnostic laboratory tests through the CLFS and for services that ordinarily require physician work through the PFS. We stated that we believe we would benefit from additional public comments on whether these tests are clinical diagnostic laboratory tests that should be paid under the CLFS or whether they are physicians' services that should be paid under the PFS. Therefore, we said that we intend to solicit comment on this issue in this proposed rule, as well as public comment on pricing policies for these tests under the CLFS at

the Annual Public Meeting. This section first discusses and requests comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, and then discusses our proposal to address payment for these CPT codes on the PFS, pending public comment on the first question. This proposal is parallel to the invitation to discuss at the CLFS Annual Public Meeting, the appropriate basis for establishing a payment amount for the molecular pathology CPT codes as clinical diagnostic laboratory tests under the CLFS.

As detailed in section II.B.1. of this proposed rule, Medicare establishes payment under the PFS by setting RVUs for physician work, practice expense (PE), and malpractice expense for services that ordinarily require physician work. To establish RVUs for physician work, we conduct a clinical review of the relative physician work (time by intensity) required for each PFS service. This clinical review includes the review of RVUs recommended by the American Medical Association Relative Value Scale Update Committee (AMA RUC) and others. The AMA RUC-recommended physician work RVUs typically are based in part on results of a survey conducted by the relevant specialty society for a service. CMS establishes RVUs for PE under a resource-based PE methodology that considers the cost of direct inputs, as well as indirect PE costs. The AMA RUC, through the Practice Expense Subcommittee, recommends direct PE inputs to CMS, and the relevant specialty societies provide pricing information for those direct inputs to CMS. After we determine the appropriate direct PE inputs, the PE methodology is used to develop proposed PE RVUs. Physician work and PE RVUs for each CPT code are constructed to reflect the typical case; that is, they reflect the service as it is furnished in greater than 50 percent of Medicare cases. CMS establishes resource-based malpractice expense RVUs using weighted specialty-specific malpractice insurance premium data collected from commercial and physician-owned insurers in CY 2010 (74 FR 61758). For most services paid under the PFS, beneficiary cost-sharing is 20 percent of the payment amount.

CMS establishes a payment rate for new clinical diagnostic laboratory tests under the CLFS by either crosswalking or gap-filling. Crosswalking is used when a new test code is comparable to an existing test code, multiple existing test codes, or a portion of an existing test code on the CLFS. Under this methodology, the new test code is assigned the local fee schedule amounts and the national limitation amount (NLA) of the existing test, with payment made at the lesser of the local fee schedule amount or the NLA. Gap-filling is used when no comparable test exists on the CLFS. In the first year, carrier-specific amounts are established for the new test code using the following sources of information: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. For the second year, the NLA is calculated, which is the median of the carrier-specific amounts. See §414.508. Services paid under the CLFS do not include any physician work, although tests paid under the CLFS can involve interpretation by a laboratory technician, a chemist, or a geneticist – none of which are occupations that meet the statutory definition of a physician. While payments can vary geographically due to contractor discretion across locality areas (which are the same localities used for the GPCIs under the PFS), payments cannot exceed a NLA nor can they be adjusted once rates are determined. In the CY 2008 PFS final rule with comment period, we adopted a prospective reconsideration process for new tests paid under the CLFS, allowing a single year for Medicare and stakeholders to review pricing for new tests after the payment is initially established (72 FR 66275 through 66279, 66401 through 66402). Finally, the statute waives beneficiary cost-sharing for clinical laboratory diagnostic tests paid on the CLFS.

For a handful of clinical laboratory services paid under the CLFS, we allow an additional payment under the PFS for the professional services of a pathologist when they meet the

requirements for clinical consultation service as defined in §415.130. The PFS pays for services that ordinarily require the work of a physician and, with regard to pathology services, explicitly pays for both the professional and technical component of the services of a pathologist as defined in §415.130 including surgical pathology, cytopathology, hematology, certain blood banking services, clinical consultations, and interpretive clinical laboratory services.

Molecular pathology tests are currently billed using combinations of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called "stacking" because different "stacks" of codes are billed depending on the components of the furnished test. Currently, all of the stacking codes are paid through the CLFS. One stacking code, CPT code 83912 (molecular diagnostics; interpretation and report) is paid on both the CLFS and the PFS. Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS using the professional component (PC, or 26) of CPT code 83912 (83912-26). Payment for the interpretation and report of a molecular pathology test when furnished by non-physician laboratory staff is made under the CLFS using CPT code 83912.

Since the creation of new molecular pathology CPT codes, there has been significant debate in the stakeholder community regarding whether these new molecular pathology codes describe physicians' services that ordinarily require physician work and would be paid under the PFS, or whether they describe clinical diagnostic laboratory tests that would be paid on the CLFS. The AMA RUC reviewed the 101 new molecular pathology CPT codes and concluded that 79 of 101 new molecular pathology codes include work furnished by a physician. The American Clinical Laboratory Association (ACLA) has indicated that 32 of the 101 new molecular pathology codes are interpreted by a physician and that a physician may perform the technical component associated with of 2 of the 101 CPT codes. Only 15 of the 101 new codes

appear on both the AMA RUC and ACLA list of codes that each believe include work furnished by a physician. Additionally, some stakeholders have suggested that all molecular pathology tests require physician interpretation and report. Other stakeholders have suggested that the interpretation and report of a molecular pathology test is not ordinarily required because the majority of the molecular pathology tests are clearly negative so interpretation and reporting generally are not necessary. In addition, some stakeholders have argued that molecular pathology tests are becoming more and more automated, and therefore generally do not require interpretation by a physician.

In the CY 2012 PFS final rule (76 FR 73190), we stated that for CY 2012, Medicare would continue to use the existing stacking codes for the reporting and payment of these molecular pathology services, and that the 101 new CPT codes would not be valid for payment for CY 2012. We did this because we were concerned that we did not have sufficient information to know whether these new molecular pathology CPT codes describe clinical diagnostic laboratory tests or services that ordinarily require physician work. For CY 2013, we continue to have many of the same concerns that led us not to recognize the 101 molecular pathology CPT codes for payment for CY 2012. Specifically, we acknowledge that we are lacking definitive answers to the following questions:

- Do each of the 101 molecular pathology CPT codes describe services that are ordinarily furnished by a physician?
- Do each of these molecular pathology CPT codes ordinarily require interpretation and report?
- What is the nature of that interpretation and does it typically require physician work?
- Who furnishes interpretation services and how frequently?

We are seeking public comment on these questions and the broader issue of whether the

new molecular pathology codes describe physicians' services that should be paid under the PFS, or if they describe clinical diagnostic laboratory tests that should be paid under the CLFS.

As we continue to consider public comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, we want to ensure that there is a payment mechanism in place to pay for these CPT codes for CY 2013. We propose to price all of the 101 new molecular pathology codes through a single fee schedule, either the CLFS or the PFS. After meeting with stakeholders and reviewing each CPT code, we believe that there is little variation in the laboratory methodologies, as all of them employ gene sequencing processes. However, there are very different processes for establishing payment rates under the PFS and the CLFS. As discussed above, Medicare sets payment under the CLFS by either crosswalking or gap-filling and, after the prospective reconsideration process, currently cannot adjust the payment amount further. In contrast, Medicare sets payment under the PFS through a set of resource-based methodologies for physician work, PE, and malpractice expense, and payment can be reviewed and adjusted as the resources required to furnish a service change. We are concerned that establishing different prices for comparable laboratory services across two different payment systems would create a financial incentive to choose one test over another simply because of its fee schedule placement. We are also concerned that the differences in prices would become more pronounced over time as the PFS continues to review the values for physician work and PE inputs relative to established CLFS prices. Therefore, because of the homogeneity of the laboratory methodologies behind these procedure test codes, we believe that it is appropriate for all 101 new molecular pathology CPT codes to be priced on the same fee schedule using the same methodology. We invite public comment on this proposal.

In our effort to determine the appropriate Medicare payment for these new molecular pathology codes, stakeholders will have the opportunity to discuss the CLFS payment basis for

establishing payment amounts for the molecular pathology codes discussed above at the CLFS Annual Public Meeting in July 2012. Section 1833(h)(8)(A) of the Act, which discusses the CLFS, requires the Secretary to "establish by regulation procedures for determining the basis for, and amount of, payment [under the CLFS] for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005." Clauses (i) and (ii) of section 1833(h)(8)(B) of the Act requires the Secretary to: 1) make "available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount… is being considered for a year;" and, "on the same day such list is made available, causes to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis… for establishing payment amounts for the tests on such list." Because we believe that these molecular pathology codes may be clinical diagnostic laboratory tests payable on the CLFS, comments and recommendations from the public on the appropriate basis for establishing payment amounts on the CLFS will be discussed at the CY 2013 CLFS Annual Public Meeting. More information on the CLFS Annual Public Meeting is available in the **Federal Register** at 77 FR 31620 through 31622 and on the CMS Website at http://www.cms.hhs.gov/ClinicalLabFeeSched.

As a parallel to our invitation to discuss these molecular pathology codes as clinical diagnostic laboratory tests at the CLFS Annual Public Meeting in July 2012, we also propose payment amounts for these codes under the PFS for CY 2013. The AMA RUC provided CMS with recommendations for physician work RVUs and PE inputs for the 79 CPT codes it believes include physician work. At our request, CAP provided CMS with direct PE input recommendations for 15 of the remaining 22 CPT codes to the best of their ability. We do not have recommendations on physician work RVUs or direct PE inputs for 7 of 101 codes which

represent tests that are patented, and therefore the methodology used to furnish the service is proprietary and has been unavailable to the AMA RUC or CMS to support developing appropriate direct PE inputs. For the 79 CPT codes, the AMA RUC-recommended physician work RVUs range from 0.13 to 2.35, with a median work RVU of 0.45. The AMA RUC-recommended physician intra-service times (which, for these codes, equals the total times) range from 7 minutes to 80 minutes, with a median intra-service time of 18 minutes. We would note that the physician work RVU for CPT code 83912-26 and all but one of the other clinical diagnostic laboratory services for which CMS recognizes payment for clinical interpretation is 0.37. Table 21 lists AMA RUC-recommended physician work RVUs and times for these services.

Molecular pathology tests can be furnished in laboratories of different types and sizes (for example a large commercial laboratory or a pathologist's office), and tests may be furnished in small or large batches. The methodologies used and resources involved in furnishing a specific test can vary from laboratory to laboratory. When developing direct PE input recommendations for CMS, CAP and the AMA RUC made assumptions about the typical laboratory setting and batch size to determine the typical direct PE inputs for each service. Given that many of these services are furnished by private laboratories, providing recommendations on the typical inputs was challenging for many services, and not possible for other services. The AMA RUC and CAP-recommended direct PE inputs are available on the CMS Website in the files supporting this CY 2013 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. We appreciate all of the effort CAP has made to develop national pricing inputs. However, we agree with its view that, in many cases, there is no established protocol for executing many of these tests and that the potential means to execute

these tests can vary considerably.

In addition to recommendations on physician work and direct PE inputs, the AMA RUC provided CMS with recommended utilization crosswalks for the 79 molecular pathology services it believes are typically furnished by a physician. When there are coding changes, the utilization crosswalk tracks Medicare utilization from an existing code to a new code. The existing code utilization figures are drawn from Medicare claims data. We use utilization crosswalk assumptions to ensure PFS BN and to create PE RVUs through the PE methodology. Currently, payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS using CPT code 83912-26. Because CPT created the new molecular pathology codes to replace the current stacking codes, when recommending utilization crosswalks, the AMA RUC started with the total utilization for CPT code 83912-26, and divided that utilization among the 79 CPT codes. CAP has indicated that it distributed the utilization based, in part, on ICD-9 diagnosis data. Table 22 lists the AMA RUC-recommended utilization crosswalks for these services.

We are concerned that the RUC-recommended utilization is too low because it is based on the utilization of CPT code 83912-26 only. Instead, we believe that the utilization assumptions for the technical component of the 101 new CPT codes should be based on the utilization of the corresponding CPT codes currently billed on the CLFS. Several laboratories provided us with a list of the molecular pathology tests that they perform, and identified the stacking codes that are currently used to bill for each test and the new CPT code that would be billed for each test. However, because the same molecular pathology test may be billed using different stacks, and the same stack may be billed for different tests, it is not possible to determine which stacks match which new CPT codes for all Medicare claims. Additionally, if a beneficiary has more than one test on the same date of service and both stacks are billed on the

same Medicare claim, it is not possible to determine which stacking codes on the claim make up each stack. Furthermore, some tests described by the new CPT codes are currently billed using general "not otherwise classified" (NOC) pathology CPT codes that capture a range of services and not just the molecular pathology tests described by the new CPT codes. Given these factors, it is difficult to estimate the utilization of the 101 new molecular pathology codes based on the Medicare billing of the current stacking and NOC codes.

If we were to finalize payment for molecular pathology services under the PFS, we do not believe that we could propose national payment rates at this time. Many outstanding questions remain including:

- If these services are furnished by a physician, what are the appropriate physician work RVUs and times relative to other similar services?
- Where and how are each of these services typically furnished—for example, what is the typical laboratory setting and batch size?
- What is the correct projected utilization for each of these services?

Given these major areas of uncertainty, if CMS determined that new molecular pathology CPT codes should be paid under the PFS for CY 2013, we are proposing to allow the Medicare contractors to price these codes because we do not believe we have sufficient information to engage in accurate national pricing and because the price of tests can vary locally. As previously discussed, this proposal is a parallel to the invitation to discuss at the CLFS Annual Public Meeting the appropriate basis for establishing a payment amount for these molecular pathology tests as clinical diagnostic laboratory tests under the CLFS. If we decide to finalize payment for these new codes under the PFS, we would consider modifying §415.130 as appropriate to provide for payment to a pathologist for molecular pathology services.

After reviewing comments received on the proposals contained within this CY 2013 PFS proposed rule, and after hearing the discussion at the CLFS Annual Public Meeting, we will determine the appropriate basis for establishing payment amounts for the new molecular pathology codes. We intend to publish our final decision in the CY 2013 PFS final rule with comment period and, at the same time that rule is published, as stated in the CLFS Public Meeting Notice, to post final payment determinations, if any, for the molecular pathology tests that will be paid under the CLFS.

**TABLE 21: AMA RUC-Recommended Physician Work RVUs and Times for New Molecular Pathology CPT Codes**

| CPT Code | Short Descriptor | AMA RUC-Recommended Physician Work RVU | AMA RUC-Recommended Physician Intra-service Time (Minutes) |
|---|---|---|---|
| 81206 | Bcr/abl1 gene major bp | 0.37 | 15 |
| 81207 | Bcr/abl1 gene minor bp | 0.15 | 11 |
| 81208 | Bcr/abl1 gene other bp | 0.46 | 18 |
| 81210 | Braf gene | 0.37 | 15 |
| 81220 | Cftr gene com variants | 0.15 | 10 |
| 81221 | Cftr gene known fam variants | 0.40 | 20 |
| 81222 | Cftr gene dup/delet variants | 0.22 | 13 |
| 81223 | Cftr gene full sequence | 0.40 | 20 |
| 81224 | Cftr gene intron poly t | 0.15 | 10 |
| 81225 | Cyp2c19 gene com variants | 0.37 | 13 |
| 81226 | Cyp2d6 gene com variants | 0.43 | 15 |
| 81227 | Cyp2c9 gene com variants | 0.38 | 14 |
| 81240 | F2 gene | 0.13 | 7 |
| 81241 | F5 gene | 0.13 | 8 |
| 81243 | Fmr1 gene detection | 0.37 | 15 |
| 81244 | Fmr1 gene characterization | 0.51 | 20 |
| 81245 | Flt3 gene | 0.37 | 15 |
| 81256 | Hfe gene | 0.13 | 7 |
| 81257 | Hba1/hba2 gene | 0.50 | 20 |
| 81261 | Igh gene rearrange amp meth | 0.52 | 21 |
| 81262 | Igh gene rearrang dir probe | 0.61 | 20 |
| 81263 | Igh vari regional mutation | 0.52 | 23 |
| 81264 | Igk rearrangeabn clonal pop | 0.58 | 22 |
| 81265 | Str markers specimen anal | 0.40 | 17 |
| 81266 | Str markers spec anal addl | 0.41 | 15 |
| 81267 | Chimerism anal no cell selec | 0.45 | 18 |
| 81268 | Chimerism anal w/cell select | 0.51 | 20 |
| 81270 | Jak2 gene | 0.15 | 10 |
| 81275 | Kras gene | 0.50 | 20 |
| 81291 | Mthfr gene | 0.15 | 10 |
| 81292 | Mlh1 gene full seq | 1.40 | 60 |
| 81293 | Mlh1 gene known variants | 0.52 | 28 |

| CPT Code | Short Descriptor | AMA RUC-Recommended Physician Work RVU | AMA RUC-Recommended Physician Intra-service Time (Minutes) |
|---|---|---|---|
| 81294 | Mlh1 gene dup/delete variant | 0.80 | 30 |
| 81295 | Msh2 gene full seq | 1.40 | 60 |
| 81296 | Msh2 gene known variants | 0.52 | 28 |
| 81297 | Msh2 gene dup/delete variant | 0.80 | 30 |
| 81298 | Msh6 gene full seq | 0.80 | 30 |
| 81299 | Msh6 gene known variants | 0.52 | 28 |
| 81300 | Msh6 gene dup/delete variant | 0.65 | 30 |
| 81301 | Microsatellite instability | 0.50 | 20 |
| 81302 | Mecp2 gene full seq | 0.65 | 30 |
| 81303 | Mecp2 gene known variant | 0.52 | 28 |
| 81304 | Mecp2 gene dup/delet variant | 0.52 | 28 |
| 81310 | Npm1 gene | 0.39 | 19 |
| 81315 | Pml/raralpha com breakpoints | 0.37 | 15 |
| 81316 | Pml/raralpha 1 breakpoint | 0.22 | 12 |
| 81317 | Pms2 gene full seq analysis | 1.40 | 60 |
| 81318 | Pms2 known familial variants | 0.52 | 28 |
| 81319 | Pms2 gene dup/delet variants | 0.80 | 30 |
| 81331 | Snrpn/ube3a gene | 0.39 | 15 |
| 81332 | Serpina1 gene | 0.40 | 15 |
| 81340 | Trb@ gene rearrange amplify | 0.63 | 25 |
| 81341 | Trb@ gene rearrange dirprobe | 0.45 | 19 |
| 81342 | Trg gene rearrangement anal | 0.57 | 25 |
| 81350 | Ugt1a1 gene | 0.37 | 15 |
| 81355 | Vkorc1 gene | 0.38 | 15 |
| 81370 | Hla i & ii typing lr | 0.54 | 15 |
| 81371 | Hla i & ii type verify lr | 0.60 | 30 |
| 81372 | Hla i typing complete lr | 0.52 | 15 |
| 81373 | Hla i typing 1 locus lr | 0.37 | 15 |
| 81374 | Hla i typing 1 antigen lr | 0.34 | 13 |
| 81375 | Hla ii typing ag equiv lr | 0.60 | 15 |
| 81376 | Hla ii typing 1 locus lr | 0.50 | 15 |
| 81377 | Hla ii type 1 ag equiv lr | 0.43 | 15 |
| 81378 | Hla i & ii typing hr | 0.45 | 20 |
| 81379 | Hla i typing complete hr | 0.45 | 15 |
| 81380 | Hla i typing 1 locus hr | 0.45 | 15 |
| 81381 | Hla i typing 1 allele hr | 0.45 | 12 |
| 81382 | Hla ii typing 1 loc hr | 0.45 | 15 |
| 81383 | Hla ii typing 1 allele hr | 0.45 | 15 |
| 81400 | Mopath procedure level 1 | 0.32 | 10 |
| 81401 | Mopath procedure level 2 | 0.40 | 15 |
| 81402 | Mopath procedure level 3 | 0.50 | 20 |
| 81403 | Mopath procedure level 4 | 0.52 | 28 |
| 81404 | Mopath procedure level 5 | 0.65 | 30 |
| 81405 | Mopath procedure level 6 | 0.80 | 30 |
| 81406 | Mopath procedure level 7 | 1.40 | 60 |
| 81407 | Mopath procedure level 8 | 1.85 | 60 |
| 81408 | Mopath procedure level 9 | 2.35 | 80 |

**TABLE 22: AMA RUC-Recommended Utilization Crosswalks for New Molecular Pathology CPT Codes**

| Source | Destination | Analytic Ratio* |
|---|---|---|
| 83912 26 | 81206 | 0.116 |
| 83912 26 | 81207 | 0.003 |
| 83912 26 | 81208 | 0.003 |
| 83912 26 | 81210 | 0.020 |
| 83912 26 | 81220 | 0.017 |
| 83912 26 | 81221 | 0.003 |
| 83912 26 | 81222 | 0.003 |
| 83912 26 | 81223 | 0.003 |
| 83912 26 | 81224 | 0.003 |
| 83912 26 | 81225 | 0.006 |
| 83912 26 | 81226 | 0.006 |
| 83912 26 | 81227 | 0.011 |
| 83912 26 | 81240 | 0.073 |
| 83912 26 | 81241 | 0.110 |
| 83912 26 | 81243 | 0.003 |
| 83912 26 | 81244 | 0.000 |
| 83912 26 | 81245 | 0.014 |
| 83912 26 | 81256 | 0.050 |
| 83912 26 | 81257 | 0.014 |
| 83912 26 | 81261 | 0.014 |
| 83912 26 | 81262 | 0.002 |
| 83912 26 | 81263 | 0.001 |
| 83912 26 | 81264 | 0.011 |
| 83912 26 | 81265 | 0.043 |
| 83912 26 | 81266 | 0.001 |
| 83912 26 | 81267 | 0.006 |
| 83912 26 | 81268 | 0.001 |
| 83912 26 | 81270 | 0.050 |
| 83912 26 | 81275 | 0.050 |
| 83912 26 | 81291 | 0.017 |
| 83912 26 | 81292 | 0.003 |
| 83912 26 | 81293 | 0.001 |
| 83912 26 | 81294 | 0.002 |
| 83912 26 | 81295 | 0.003 |
| 83912 26 | 81296 | 0.001 |
| 83912 26 | 81297 | 0.002 |
| 83912 26 | 81298 | 0.001 |
| 83912 26 | 81299 | 0.002 |
| 83912 26 | 81300 | 0.001 |
| 83912 26 | 81301 | 0.003 |
| 83912 26 | 81302 | 0.001 |
| 83912 26 | 81303 | 0.000 |
| 83912 26 | 81304 | 0.000 |
| 83912 26 | 81310 | 0.014 |
| 83912 26 | 81315 | 0.017 |
| 83912 26 | 81316 | 0.003 |
| 83912 26 | 81317 | 0.002 |
| 83912 26 | 81318 | 0.001 |
| 83912 26 | 81319 | 0.001 |
| 83912 26 | 81331 | 0.001 |
| 83912 26 | 81332 | 0.003 |
| 83912 26 | 81340 | 0.011 |
| 83912 26 | 81341 | 0.003 |
| 83912 26 | 81342 | 0.017 |
| 83912 26 | 81350 | 0.002 |
| 83912 26 | 81355 | 0.011 |
| 83912 26 | 81370 | 0.043 |
| 83912 26 | 81371 | 0.029 |
| 83912 26 | 81372 | 0.011 |
| 83912 26 | 81373 | 0.011 |
| 83912 26 | 81374 | 0.029 |
| 83912 26 | 81375 | 0.006 |
| 83912 26 | 81376 | 0.006 |
| 83912 26 | 81377 | 0.006 |
| 83912 26 | 81378 | 0.006 |
| 83912 26 | 81379 | 0.003 |
| 83912 26 | 81380 | 0.003 |
| 83912 26 | 81381 | 0.003 |
| 83912 26 | 81382 | 0.003 |
| 83912 26 | 81383 | 0.003 |
| 83912 26 | 81400 | 0.007 |
| 83912 26 | 81401 | 0.007 |
| 83912 26 | 81402 | 0.007 |
| 83912 26 | 81403 | 0.007 |
| 83912 26 | 81404 | 0.007 |
| 83912 26 | 81405 | 0.007 |
| 83912 26 | 81406 | 0.003 |
| 83912 26 | 81407 | 0.003 |
| 83912 26 | 81408 | 0.003 |

*Percentage of source code utilization transferred to the destination code

J. Payment for New Preventive Service HCPCS G-Codes

Under section 1861(ddd) of the Act, as amended by Section 4105 of the Affordable Care Act, CMS is authorized to add coverage of "additional preventive services" if certain statutory criteria are met as determined through the national coverage determination (NCD) process, including that the service meets all of the following criteria: (1) they must be reasonable and necessary for the prevention or early detection of illness or disability, (2) they must be recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) they must be appropriate for individuals entitled to benefits under Part A or enrolled under Part B. After reviewing the USPSTF recommendations for the preventive services, conducting evidence reviews, and considering public comments under the NCD process, we determined that the above criteria were met for the services listed in Table 23. Medicare now covers each of the following preventive services:

- Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse, effective October 14, 2011;
- Screening for Depression in Adults, effective October 14, 2011;
- Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs, effective November 8, 2011;
- Intensive Behavioral Therapy for Cardiovascular Disease, effective November 8, 2011; and
- Intensive Behavioral Therapy for Obesity, effective November 29, 2011.

Table 23 lists the HCPCS G-codes created for reporting and payment of these services. The Medicare PFS payment rates for these services are discussed below. The NCD process establishing coverage of these preventive services was not complete at the time of publication of the CY 2012 PFS final rule in early November, so we could not indicate interim RVUs for these

preventive services in our final rule addenda. However, we were able to include HCPCS G-codes and national payment amounts for these services in the CY 2012 PFS national relative value files, which became available at the end of the year and were effective January 1, 2012. From the effective date of each service to December 31, 2011, the payment amount for these codes was established by the Medicare Administrative Contractors.

**TABLE 23: New Preventive Service HCPCS G-Codes**

| HCPCS Code | HCPCS Code Long Descriptor | CMS National Coverage Determination (NCD) | CMS Change Request (CR) |
|---|---|---|---|
| G0442 | Annual alcohol misuse screening, 15 minutes | Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8) | CR7633 |
| G0443 | Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes | Screening Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8) | CR7633 |
| G0444 | Annual Depression Screening, 15 minutes | Screening for Depression in Adults (NCD 210.9) | CR7637 |
| G0445 | High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior; performed semi-annually, 30 minutes | Screening for Sexually Transmitted infections(STIs) and High- Intensity Behavioral Counseling (HIBC) to prevent STIs (NCD 210.10) | CR7610 |
| G0446 | Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes | Intensive Behavioral Therapy for Cardiovascular Disease (NCD 210.11) | CR7636 |
| G0447 | Face-to-face behavioral counseling for obesity, 15 minutes | Intensive Behavioral Therapy for Obesity (NCD 210.12) | CR7641 |

Two new HCPCS codes, G0442 (Annual alcohol misuse screening, 15 minutes), and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes), were created for the reporting and payment of screening and behavioral counseling interventions in primary care to reduce alcohol misuse.

We believe that the screening service described by HCPCS code G0442 requires similar physician work as CPT code 99211 (Level 1 office or other outpatient visit, established patient), that may not require the presence of a physician. CPT code 99211 has a work RVU of 0.18 and we believe HCPCS code G0442 should be valued similarly. As such, we are proposing a work RVU of 0.18 for HCPCS code G0442 for CY 2013. For physician time, we are proposing 15

minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We request public comment on these CY 2013 proposed values for HCPCS code G0442, which are the same as the current (CY 2012) values for this service.

We believe that the behavioral counseling service described by HCPCS code G0443 requires similar physician work to CPT code 97803 (Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes) (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0443 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We request public comment on these CY 2013 proposed values for HCPCS code G0443, which are the same as the current (CY 2012) values for this service.

HCPCS code G0444 (Annual Depression Screening, 15 minutes) was created for the reporting and payment of screening for depression in adults.

We believe that the screening service described by HCPCS code G0444 requires similar physician work as CPT code 99211 (work RVU = 0.18) and should be valued similarly. As such, we are proposing a work RVU of 0.18 for HCPCS code G0444 for CY 2013. For

physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We request public comment on these CY 2013 proposed values for HCPCS code G0444, which are the same as the current (CY 2012) values for this service.

HCPCS code G0445 (high-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior, performed semi-annually, 30 minutes) was created for the reporting and payment of HIBC to prevent STIs.

We believe that the behavioral counseling service described by HCPCS code G0445 requires similar physician work to CPT code 97803 (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0445 for CY 2013. For physician time, we are proposing 30 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We request public comment on these CY 2013 proposed values for HCPCS code G0445, which are the same as the current (CY 2012) values for this service.

HCPCS code G0446 (Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes) was created for the reporting and payment of intensive behavioral therapy for cardiovascular disease.

We believe that the behavioral therapy service described by HCPCS code G0446 requires similar physician work to CPT code 97803 (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0446 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We request public comment on these CY 2013 proposed values for HCPCS code G0446, which are the same as the current (CY 2012) values for this service.

HCPCS G0447 (Face-to-face behavioral counseling for obesity, 15 minutes) was created for the reporting and payment of intensive behavioral therapy for obesity.

We believe that the behavioral counseling service described by HCPCS code G0447 requires similar physician work to CPT code 97803 (work RVU = 0.45) and should be valued similarly. As such, we are proposing a work RVU of 0.45 for HCPCS code G0447 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 97803. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Website under the downloads for the CY 2013 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. We request public comment on these CY 2013 proposed values for HCPCS code G0447, which are the same as the current (CY 2012) values for this service.

K. Certified Registered Nurse Anesthetists and Chronic Pain Management Services

The benefit category for services furnished by a certified registered nurse anesthetist (CRNA) was added to Medicare by section 9320 of the Omnibus Budget Reconciliation Act (OBRA) 1986. Since this benefit was implemented on January 1, 1989, CRNAs have been eligible to bill Medicare directly for the specified services. Section 1861(bb)(2) of the Act defines a CRNA as "a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists."

Section 410.69(b) defines a CRNA as a registered nurse who: (1) is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to nonphysician anesthetists; (3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets one of the following criteria: (i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

Section 1861(bb)(1) of the Act defines services of a CRNA as "anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished". CRNAs are paid at the same rate as physicians for furnishing such

services to Medicare beneficiaries. Payment for services furnished by CRNAs only differs from physicians in that payment to CRNAs is made only on an assignment-related basis (§414.60) and supervision requirements apply in certain circumstances.

At the time that the Medicare benefit for CRNA services was established, CRNA practice largely occurred in the surgical setting and services other than anesthesia (medical and surgical) were furnished in the immediate pre- and post-surgery timeframe. The scope of "anesthesia services and related care" as delineated in section 1861(bb)(1) of the Act reflected that practice standard. As CRNAs have moved into other practice settings, questions have arisen regarding what services are encompassed under the "related care" aspect of the benefit category. Specifically, some CRNAs now offer chronic pain management services that are separate and distinct from a surgical procedure. Changes in CRNA practice have prompted questions as to whether these services fall within the scope of section 1861(bb)(1) of the Act. Medicare Administrative Contractors (MACs) have reached different conclusions as to whether the statutory description of "anesthesia services and related care" encompasses the chronic pain management services delivered by CRNAs. As a result, we have been asked to address whether or not chronic pain management is included within the scope of the statutory benefit for CRNA services.

To determine whether chronic pain management is included in the statutory benefit for CRNA services, we reviewed our current regulations and subregulatory guidance. We found that the existing guidance does not specifically address chronic pain management. In the Internet Only Manual (Pub 100-04, Ch 12, Sec 140.4.3), we discuss the medical or surgical services that fall under the "related care" language stating, "These may include the insertion of Swan Ganz catheters, central venous pressure lines, pain management, emergency intubation, and the pre-anesthetic examination and evaluation of a patient who does not undergo surgery." Some have

interpreted the reference to "pain management" in this language as authorizing direct payment to CRNAs for chronic pain management services, while others have taken the view that the services highlighted in the manual language are services furnished in the perioperative setting and refer only to acute pain management associated with the surgical procedure.

Since existing guidance was not determinative, we assessed the issue of CRNA practice of chronic pain management more broadly. We found that chronic pain management is an emerging field. The Institute of Medicine (IOM) issued a report entitled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research" on June 29, 2011, discussing the importance of pain management and focusing on the many challenges in delivering effective chronic pain management. The available interventions to treat chronic pain have been expanding. In addition to the use of medications and a variety of diagnostic tests, techniques include neural blocks, neuromodulatory techniques, and implanted pain management devices. The healthcare community continues to examine the appropriateness and effectiveness of these many and varied treatment techniques and modalities. As part of this evolution, Medicare established a physician specialty code for interventional pain management in 2003.

The healthcare community continues to debate whether CRNAs are qualified to provide chronic pain management. Some have stated that interventional pain management for beneficiaries with chronic pain is the practice of medicine, that CRNAs do not receive the sufficient education on chronic pain management, and that CRNAs do not have the skills required to furnish chronic pain management services. Others have stated that both acute and chronic pain management and treatment are within the CRNA professional scope and are comparable services, and that CRNAs receive the clinical training and experience necessary to furnish both acute and chronic pain management services. Recently, several State legislatures

have debated the scope of CRNA practice, including those in the States of California, Colorado, Missouri, South Carolina, Nevada, and Virginia.

In the context of Medicare, some have pointed to Medicare policies allowing other advanced practice nurses such as nurse practitioners or clinical nurse specialists to furnish and bill for physicians' services as support for recognizing a broader interpretation of the scope of CRNA practice. We would note that the statutory benefit category definition for CRNAs substantively differs from that for other advanced practice nurses. Section 1861(s)(2)(K) of the Act authorizes certain nonphysician practitioners (NPPs) to bill Medicare directly for services they are legally authorized to perform under State law, and "which would be physicians' services if furnished by a physician." With certain conditions (such as physician supervision or collaboration), the statute allows these NPPs to bill Medicare for physicians' services that fall within their State scope of practice.

Since State governments regulate the licensure and practice of specific types of health care professionals, we have looked to the State scope of practice laws to determine if chronic pain management was within the scope of practice for CRNAs. State scope of practice laws vary with regard to the range of services that CRNAs may perform, and some include chronic pain management. As discussed earlier, several States are debating whether to include chronic pain management services within the CRNA scope of practice.

After assessing the information available to us, we have concluded that chronic pain management is an evolving field, and we recognize that certain States have determined that the scope of practice for a CRNA should include chronic pain management in order to meet health care needs of their residents and ensure their health and safety. Therefore, we propose to revise our regulations at §410.69(b) to define the statutory description of CRNA services. Specifically, we propose to add the following language: "Anesthesia and related care includes medical and

surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the State in which the services are furnished." This proposed definition would set a Medicare standard for the services that can be furnished and billed by CRNAs while allowing appropriate flexibility to meet the unique needs of each State. The proposal also dovetails with the language in section 1861(bb)(1) of the Act requiring the State's legal authorization to perform CRNA services as a key component of the CRNA benefit category. Finally, the proposed definition is also consistent with our policy to recognize State scope of practice as one parameter defining the services that can be furnished and billed by other NPPs.

Simply because the State allows a certain type of health care professional to furnish certain services does not mean that all members of that profession are adequately trained to provide the service. In the case of chronic pain management, the IOM report specifically noted that many practitioners lack the skills needed to help patients with the day-to-day self-management that is required to properly serve individuals with chronic pain. As with all practitioners who furnish services to Medicare beneficiaries, CRNAs practicing in States that allow them to furnish chronic pain management services are responsible for obtaining the necessary training for any and all services furnished to Medicare beneficiaries.

L. Ordering of Portable X-Ray Services

Portable x-ray suppliers provide diagnostic imaging services at a patient's location. These services are most often furnished in residences, including private homes and group living facilities (for example, nursing homes) rather than in a traditional clinical setting (for example, a doctor's office or hospital). The supplier transports mobile diagnostic imaging equipment to the patient's location, sets up the equipment, and administers the test onsite. The supplier may interpret the results itself or it may provide the results to an outside physician for interpretation.

Portable x-ray services may avoid the need for expensive ambulance transport of frail patients to a radiology facility or hospital.

In the Medicare Conditions for Coverage regulations established in 1969, §486.106(a), requires that "portable x-ray examinations are performed only on the order of a doctor of medicine (MD) or doctor of osteopathy (DO) licensed to practice in the State…" With the exception of portable x-ray services, Medicare payment regulations at §410.32 allow physicians, including limited-license practitioners such as doctors of podiatry and optometry, and most nonphysician practitioners who furnish physicians' services to order diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests so long as those nonphysician practitioners are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit.

Nonphysician practitioners have become an increasingly important component of clinical care, and we believe that delivery systems should take full advantage of all members of a healthcare team, including nonphysician practitioners.

Although current Medicare regulations limit ordering of portable x-ray services to a MD or a DO, the Office of the Inspector General (OIG) in its December 2011 report entitled "Questionable Billing Patterns of Portable X-Ray Suppliers" (OEI-12-10-00190) found that Medicare was paying for portable x-ray services ordered by physicians other than MDs and DOs, including podiatrists and chiropractors, and by nonphysician practitioners. We issued a special education article on January 20, 2012, through the Medicare Learning Network (MLN) "Important Reminder for Providers and Suppliers Who Provide Services and Items Ordered or Referred by Other Providers and Suppliers," reiterating our current policy that portable x-ray services can only be ordered by a MD or DO. The article is available at http://www.cms.gov/MLNMattersArticles/downloads/SE1201.pdf on the CMS Website. Since

the publication of the above mentioned article, several stakeholders have told us that members of the healthcare community fail to distinguish ordering for portable x-ray services from ordering for other diagnostic services where our general policy is to allow nonphysician practitioners and physicians other than MDs and DOs to order diagnostic tests within the scope of their authority under State law and their Medicare statutory benefit. They report finding the different requirements confusing.

We propose to revise our current regulations, which limit ordering of portable x-ray services to only a MD or DO, to allow other physicians and nonphysician practitioners acting within the scope of their Medicare benefit and State law to order portable x-ray services. Specifically, we propose revisions to the Conditions for Coverage at §486.106(a) and §486.106(b) to permit portable x-ray services to be ordered by a physician or nonphysician practitioner in accordance with the ordering policies for other diagnostic services under §410.32(a).

This proposed change would allow a MD or DO, as well as an nurse practitioner, clinical nurse specialist, physician assistant, certified nurse-midwife, doctor of optometry, doctor of dental surgery and doctor of dental medicine, doctor of podiatric medicine, clinical psychologist, and clinical social worker to order portable x-ray services within their State scope of practice and the scope of their Medicare benefit. Although all of these physicians and nonphysician practitioners are authorized to order diagnostic services in accordance with §410.32(a), their Medicare benefit delimits the services that they can provide.

We also propose to revise the language included in §410.32(c) to recognize the same authority for physicians and nonphysician practitioners to order diagnostic tests as is prescribed for other diagnostic services in §410.32(a). Finally, we are proposing two technical corrections. One is to §410.32(d)(2), where we currently cite to subsection (a)(3) for the definition of

qualified nonphysician practitioner. The definition of qualified nonphysician practitioner is in paragraph (a)(2) and paragraph (a)(3) does not exist; therefore, we are changing the citation to the correct citation. The second technical correction is §410.32(b)(2)(iii) to better reflect statutory authority to provide neuropsychological testing in addition to psychological testing.

Although we believe that this proposal is appropriate given overall changes in practice patterns since the beginning of the Medicare program, we remain concerned about the OIG's recent findings. The OIG observed questionable billing patterns for portable x-ray services in addition to ordering by nonphysician practitioners. Of specific note was the observation that some portable x-ray suppliers are delivering services on the same day that the patient also receives services in a clinical setting, such as the physician office or hospital. Under our current regulation at §486.106(a)(2), the order for portable x-ray services must include a statement concerning the condition of the patient which indicates why portable x-ray services are necessary. If the patient was able, on the same day that a portable x-ray service was furnished, to travel safely to a clinical setting, the statement of need for portable x-ray services could be questionable. We also are concerned that the OIG observed some portable x-ray suppliers billing for multiple trips to a facility. Medicare makes a single payment for each trip the portable x-ray supplier makes to a particular location. We make available multiple modifiers to allow the portable x-ray supplier to indicate the number of patients served on a single trip to a facility. We expect portable x-ray suppliers to use those modifiers and not to bill multiple trips to the same facility when only one trip was made. Additionally, we strongly encourage portable x-ray suppliers to make efficient use of resources and consolidate trips rather than making multiple trips on the same day as clinically appropriate.

In conjunction with our proposal to expand the scope of physicians and nonphysician practitioners who can order portable x-ray services, we intend to develop, as needed, monitoring

standards predicated by these and other OIG findings. In addition, we will be conducting data analysis of ordering patterns for portable x-ray and other diagnostic services to determine if additional claims edits, provider audits, or fraud investigations are required to prevent abuse of this service and to allow for the collection of any potential overpayments. We encourage providers, as with any diagnostic test, to proactively determine and document the medical necessity for this testing.

We are also considering whether to make other revisions to the current regulations at 42 CFR, Part 486, Subpart C—Conditions for Coverage: Portable X-Ray Services through future rulemaking, as we are aware stakeholders have suggested regulatory changes to consider since the last update of this regulation. The last time this regulation was updated was in 2008, but many of the sections in Part 486, Subpart C have not been updated since 1995. Since we are proposing to update part of Part 486, Subpart C in this proposed rule, we are using this opportunity to seek public comment on suggestions for updating in the future the rest of the regulations at Part 486, Subpart C. We are open to all suggestions for updates; therefore we did not pose specific questions for response by the public.

We are specifically seeking public comment on suggestions for updating Subpart C—Conditions for Coverage: Portable X-Ray Services; noting that any regulatory changes would be addressed through separate notice-and-comment rulemaking.

## III. Other Provisions of the Proposed Regulation

A. 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) (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 (75 FR 73385 and 73386, 73625), we revised §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 106(a) of the 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, 70315), we revised §414.610(c) (1) (ii) to

conform the regulations to this statutory requirement. However, in doing so, paragraphs (c)(1)(ii)(A) and (B) were inadvertently deleted from the Code of Federal Regulations. Therefore, we propose to reinstate paragraphs (c)(1)(ii)(A) and (B), as further revised below to conform to subsequent legislation.

Subsequently, section 306 (a) of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112-78) (TPTCCA) 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) (MCTRJCA) further amended section 1834(l)(13)(A) to extend these payment add-ons through December 31, 2012. Thus, these payment add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2012 and before January 1, 2013. Accordingly, we are proposing to revise §414.610(c)(1)(ii) to conform the regulations to these statutory requirements. These statutory requirements are self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

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

Section 146(b) (1) of the MIPPA amended the designation of 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 through 86, 73625 through 26), 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 through 70285, 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. Therefore, we are proposing to revise §414.610(h) to conform the regulations to these statutory requirements. These statutory requirements are 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 December 31, 2012.

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

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added paragraph (12) to section 1834(l) of 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 (75 FR 73385 through 73386 and 73625), we revised §414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA again 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 through 70285, 70315), we revised §414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Subsequently, 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. 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, 2012 and before January 1, 2013 where transportation originates in a qualified rural area.

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.

Accordingly, we are proposing to revise §414.610(c)(5)(ii) to conform the regulations to the statutory requirements set forth at section 306(c) of the TPTCCA and section 3007(c) of the MCTRJCA. These statutory requirements are self-implementing. Together, these provisions require a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2012, and does not require any substantive exercise of discretion on the part of the Secretary.

B. Part B Drug Payment: Average Sales Price (ASP) Issues

Section 1847A of the Act requires use of the average sales price (ASP) payment methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology applies to most drugs furnished incident to a physician's service, many drugs furnished under the DME benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

1. Widely Available Market Price (WAMP)/Average Manufacturer Price (AMP) price substitution

For a drug or biological that is found to have exceeded the WAMP of AMP by a threshold percentage, section 1847A(d)(3)(C) of the Act authorizes the Secretary to substitute, the lesser of --

- The widely available market price for the drug or biological, or
- 103 percent of the average manufacturer price as determined under section 1927(k)(1) of the Act."

The applicable threshold percentage is specified in section 1847A(d)(3)(B)(i) of the Act as 5 percent for CY 2005. For CY 2006 and subsequent years, section 1847A(d)(3)(B)(ii) of the

Act authorizes the Secretary to specify the threshold percentage for the WAMP or the AMP, or both. In the CY 2006 (70 FR 70222), CY 2007 (71 FR69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904) PFS final rules with comment period, we specified an applicable threshold percentage of 5 percent for both the WAMP and AMP. We based this decision on the fact that data was too limited to support an adjustment to the 5 percent threshold. Beginning in CY 2011, we treated the WAMP and AMP based adjustments to the applicable threshold percentages separately.

a. WAMP Threshold and Price Substitution

After soliciting and reviewing comments, we finalized proposals to continue the 5 percent WAMP threshold for CY 2011 (75 FR 73469), and CY 2012 (76 FR 73287). For CY 2013, we again have no additional information from OIG studies or other sources that leads us to consider an alternative threshold. When making comparisons to the WAMP, we propose that the applicable threshold percentage remain at 5 percent until such time that a change in the threshold amount is warranted, and we propose to update §414.904(d)(3)(iv) accordingly. As mentioned above, the threshold has remained at 5 percent since 2005. Our proposal will eliminate the need for annual rulemaking until a change is warranted.

We are not proposing to make any WAMP based price substitutions at this time. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73470) and reiterated in CY 2012 (76 FR 73287), we understand that there are complicated operational issues associated with the WAMP based substitution policy, and we continue to proceed cautiously in this area. We remain committed to providing stakeholders, including providers and manufacturers of drugs impacted by potential price substitutions with adequate notice of our intentions, including the opportunity to provide input with regard to the processes for substituting the WAMP for the ASP.

b. AMP Threshold

Like the WAMP threshold, for CY 2013, we have no information that leads us to believe that the 5 percent threshold percentage for AMP-based price substitution is inappropriate or should be changed. We propose that the applicable threshold percentage remain at 5 percent until such time that a change in the threshold amount is warranted, and we propose to update §414.904(d)(3)(iii) accordingly. The AMP threshold has remained at 5 percent since 2005. Our proposal will eliminate the need for annual rulemaking until a change is warranted.

c. AMP Price Substitution-Additional condition

In the CY 2012 PFS rule, we specified that the substitution of AMP for ASP will be made only when the ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter, and that matching sets of NDCs had to be used in the comparison (76FR 73289 through 73295). The value of the AMP based price substation must also be less than the ASP payment limit that is calculated for the quarter in which the substitution is applied.

We did not apply the price substitution policy in April 2012 because access concerns led us to reconsider whether it was prudent to proceed with price substitution during a developing situation that was related to a drug shortage that had not met the definition of a public health emergency under section 1847A(e) of the Act. In light of recent concerns about drug shortages, the resulting impact on patient care, beneficiary and provider access, as well as the potential for shortages to suddenly affect drug prices for the provider, under the authority in section 1847A(d)(3)(C) of the Act, we propose adding §414.904(d)(3)(ii)(C) that would prevent the AMP price substitution policy from taking effect if the drug and dosage form represented by the HCPCS code are reported by the FDA on their Current Drug Shortage list (or other FDA reporting tool that identifies shortages of critical or medically necessary drugs) to be in short

supply at the time that ASP payment limits are being finalized for the next quarter. Further, we also would like to clarify that this proposal to add to the safeguards finalized in CY 2012 only applies to calculations under the AMP-based price substitution policy. Our proposal is intended to continue the cautious approach described in previous rules and to strike a balance between operational requirements associated with receiving manufacturers' ASP reports, calculating the payment limits, and posting stable payment limits that will be used to pay claims. We believe that this proposal also addresses concerns about access to care, known program issues identified by the OIG, and provides an opportunity for some modest program savings. At this time, we are not proposing any other changes to the safeguards, timing, or notification that identifies the codes that will be substituted each quarter. We welcome comments on our approach as well as comments regarding additional specific safeguards for the AMP price substitution policy.

2. Billing for Part B Drugs Administered Incident to Physicians' Services.

In this section, we propose to clarify payment policies regarding billing for certain drugs under Medicare Part B. In 2010 and 2011, we issued two change requests (CRs 7109 and 7397) that summarized a number of longstanding drug payment policy and billing requirements. We considered these CRs to be merely clarifying, rather than changing, our policy. However, one item in the CRs, which stated that pharmacies may not bill for drugs that are used incident to physicians' service, has caused some concern. Specifically, we understand that some nonphysician suppliers – operating in part on the basis of guidance from a Medicare contractor – have been submitting claims for drugs that they have shipped to physicians' offices for use in refilling implanted intrathecal pumps. In light of concern over its potential effect on suppliers, we delayed implementation of the most recently updated CR (CR 7397 Transmittal 2437, April 4, 2012) until January 1, 2013 so that we could undertake rulemaking, evaluate public comments

on this issue, and determine whether CR 7397 should be implemented as planned, revised, or rescinded.

Implanted pumps may qualify as Durable Medical Equipment (DME); however, unlike external pumps used to administer drugs, implanted pumps are typically refilled in a physician's office. The implanted intrathecal pump is refilled by injecting the drug into a pump's reservoir, which lies below the patient's skin. The reservoir is connected to the pump, which delivers the drug to the intrathecal space through a tunneled catheter. The procedure of refilling an intrathecal pain pump is a service that is typically performed by the physician because of risk and complexity.

To be covered by Medicare, an item or service must fall within one or more benefit categories within Part A or Part B, and must not be otherwise excluded from coverage. Drugs and biologicals paid under Medicare part B drugs fall into three basic categories as follows:

- Drugs furnished "incident to" a physician's services: These are typically injectable drugs that are bought by the physician, administered in the physician's office and then billed by the physician to the Medicare Administrative Contractor (MAC).
- Drugs administered through a covered item of DME: These drugs are supplies necessary for the effective use of DME and are typically furnished to the beneficiary by suppliers that are either pharmacies (or general DME suppliers that utilize licensed pharmacists) for administration in a setting other than the physician's office. Most DME drugs are billed to the DME MAC.
- Drugs specified by the statute: Include a variety of drugs, such as oral immunosuppressives and certain vaccines.

Drugs used to refill an implanted intrathecal pump can be considered to be within either the "incident to" or the DME benefit category. The CMS Benefit Policy Manual (100-02

Chapter 15 Section 50.3) states that drugs paid under the "incident to" provision are of a form that is not usually self-administered; are furnished by a physician; and are administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. In what we believe is a typical situation, when physicians' services are used to refill an intrathecal pump, the "incident to" requirements can be met because, consistent with our guidance and longstanding policy, the physician or other professional employed by his or her office performs a procedure to inject the drug into the implanted pump's reservoir (that is, the drug is not self-administered) and the drug represents a cost to the physician because he or she has purchased it.

Conversely, we believe that in the typical situation, payment to a pharmacy or other nonphysician supplier under the DME benefit for a drug dispensed for use in the physician's office is both inappropriate and inconsistent with existing guidance. For example, DME prosthetics, orthotics, and supplies (POS) policy does not permit payment for prosthetics dispensed prior to a procedure. Moreover, in the case of prescription drugs used in conjunction with DME, our guidance is clear that the entity that dispenses the drug needs to furnish it directly to the patient for whom a prescription is written. We do not believe that an arrangement whereby a pharmacy (or supplier) ships a drug to a physician's office for administration to a patient constitutes furnishing the drug directly to the patient.

We note that payment to pharmacies (or suppliers) for drugs used to refill an implanted pump can be made under the DME benefit category where the drug is dispensed to a patient and the implanted pump is refilled without a physician's service. However, it is our understanding that implanted pumps are rarely refilled without utilizing the service of a physician.

We are concerned about stakeholders' reports that, due to guidance from a contractor, Medicare payment policy on this issue has been applied in an inconsistent manner. We consider

the contractor's guidance to be erroneous. This inconsistency has permitted supplier claims for drugs dispensed by pharmacies to physicians' offices to be paid in some jurisdictions and has denied such payment in others. We understand that the inconsistent application of our payment policy has influenced the business and professional practices of pharmacies/DME suppliers that prepare drugs for implanted pumps. However, we do not believe that payment for drugs used to refill implanted DME should continue to be made because such action is not supported under long standing policy and, as discussed above, is not appropriate.

We therefore propose to clarify that we consider drugs used by a physician to refill an implantable item of DME to be within the "incident to" benefit category and not the DME benefit category. Therefore, the physician must buy and bill for the drug, and a non-physician supplier that has shipped the drug to the physician's office may not do so (except as may be permitted pursuant to a valid reassignment). We welcome comments on this proposal and its potential impact on beneficiaries and providers.

C. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

1. Background

Sections 1832, 1834, and 1861 of the Act establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to require, for specified covered items, that payment may only be made under section 1834(a) of the Act if a physician has communicated to the supplier a written order for the item, before delivery of the item. Section 1834(h)(3) of the Act states that section 1834(a)(11) applies to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of durable medical equipment (DME). In a December 7, 1992 final rule (57 FR 57675), we implemented this provision in §410.38(g), for DME items and §410.36(b) for prosthetic devices, orthotics, and prosthetics. Both of these sections state that as a requirement for payment, CMS, a carrier, or, more recently, a Medicare Administrative Contractor (MAC) may determine that an item of DME requires a written physician order before delivery. In addition to our regulations at §410.38(g) and §410.36(b), we have stated in Chapter 5, Section 5.2.3.1 of the Program Integrity Manual, that the following items require a written order prior to delivery: (1) pressure reducing pads, mattress overlays, mattresses, and beds; (2) seatlift mechanisms; (3) transcutaneous electrical nerve stimulation (TENS) units; (4) power operated vehicles (POVs) and power wheelchairs.

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act. It added language that requires a written order for certain items of DME, which under section 1834(h)(3) of the Act also could include prosthetic devices, orthotics, and prosthetics, to be

issued per a physician documenting that a physician, a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary. The encounter must occur during the 6 months prior to the written order for each item or during such other reasonable timeframe as specified by the Secretary.

2. Provisions of the Proposed Regulations

a. DME Face-to-Face Encounters

(1) General Requirements

We are proposing to first revise §410.38(g) to require, as a condition of payment for certain covered items of DME, that a physician must have documented and communicated to the DME supplier that the physician or a PA, an NP, or a CNS has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written.

We make this proposal because we believe that a face-to-face encounter that occurs within 90 days prior to the written order for DME should be relevant to the reason for the beneficiary's need for the item of DME, and therefore, this face-to-face encounter should substantiate that the beneficiary's condition warrants the covered item of DME and be sufficient to meet the goals of this statutory requirement. However, we recognize that there may be circumstances when it may not be possible to meet this general requirement of "prior to the written order," and that in such cases, beneficiary access to needed items must be protected. If a face-to-face encounter occurs within 90 days of the written order, but is not related to the condition warranting the need for the item of DME, or if the beneficiary has not seen the physician or PA, NP, or CNS within the 90 days prior to the written order, we propose to allow a face-to-face encounter up to and including 30 days after the order is written in order to ensure access to needed items.

During the face-to-face encounter the physician, a PA, a, NP, or a CNS must have evaluated the beneficiary, conducted a needs assessment for the beneficiary or treated the beneficiary for the medical condition that supports the need for each covered item of DME. As a matter of practice, this information would be part of the beneficiary's medical record, which identifies the practitioner who provided the face-to-face assessment. We believe that requiring a face-to-face encounter that supports the need for the covered item of DME would reduce the risk of fraud, waste, and abuse since these visits would help ensure that a beneficiary's condition warrants the covered item of DME.

Section 1834(a)(11)(B)(ii) of the Act, as amended by section 6407(b) of the Affordable Care Act states that a physician must document that the physician, a PA, a NP, or a CNS has had a face-to-face encounter (other than with respect to encounters that are incident to services involved) with the beneficiary. Incident to services are defined in section *1861*(*s*)(*2*)(A) of the Act. Likewise, for the purpose of this regulation, a face-to-face encounter must be documented by a physician and any encounter that is covered as an "incident to" service does not satisfy the requirements of this regulation.

We note that a face-to-face encounter may be accomplished via a telehealth encounter if all Medicare telehealth requirements as defined under section 1834(m) of the Act and the implementing regulations in §410.78 and §414.65 are met. Specifically, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in an originating site. The requirements in this proposed rule do not supersede the requirements of telehealth and merely apply to the telehealth benefit where applicable. In general, originating sites must be located in a rural health professional shortage area (HPSA) or in a county outside of a metropolitan statistical area (MSA). The practitioner at the distant site may be a physician, PA, NP, or CNS, and the encounter must be reported with a healthcare procedure common coding system (HCPCS) code

for a service on the list of approved Medicare telehealth services for the applicable year. In the May 5, 2010 **Federal Register** (76 FR 25550), we published a final rule that revised the conditions of participation (CoPs) for hospitals and critical access hospitals (CAHs). These revisions implement a new credentialing and privileging process for physicians and other practitioners providing telemedicine services. We refer readers to the CMS Website for more information regarding telehealth services at http://www.cms.gov/Telehealth/.

A single face-to-face encounter, including those facilitated through the appropriate use of telehealth, can support the need for multiple covered items of DME as long as it is clearly documented in the pertinent medical record that the beneficiary was evaluated or treated for a condition that supports the need for each covered item of DME, during the specified period of time.

To promote the authenticity and comprehensiveness of the written order and as part of our efforts to reduce the risk of waste, fraud, and abuse, we propose that as a condition of payment a written order must include: (1) the beneficiary name; (2) the item of DME ordered; (3) prescribing practitioner NPI; (4) the signature of the prescribing practitioner; (5) the date of the order; (6) the diagnosis; and (7) necessary proper usage instructions, as applicable. Examples of necessary proper usage instruction could include duration of use, method of utilization, and correct positioning. We recognize that standards of practice may require that orders contain additional information. However, for purposes of this proposed rule, which is focused on implementing section 1834(a)(11)(B) of the Act and reducing fraud, waste, and abuse, an order without these minimum elements would be considered incomplete and would not support a claim for payment. We believe including this information on the written order would be a safeguard against waste, fraud, and abuse by promoting authenticity and comprehensiveness of the order by the practitioner.

Based on our commitment to the general principles of the President's Executive Order entitled "Improving Regulation and Regulatory Review" (released January 18, 2011) and to be consistent with other provisions in the amendments made by section 6407(a) of the Affordable Care Act and the provisions of section 6407 (d) of the Affordable Care Act as discussed above, we are proposing to require that the face-to-face encounter occur no earlier than 90 days prior to each written order for a covered item of DME or within 30 days after the order is written. This proposal is consistent with the Medicare and Medicaid home health face-to-face requirement which increases physician accountability and specifies a timeframe within the discretion of the Secretary. (For more information on the Medicare and Medicaid home health face-to-face requirements see the November 17, 2010 final rule (75 FR 70372) and the July 12, 2011 proposed rule (76 FR 41032) for Medicare and Medicaid respectively.) We have exercised our discretion to set a timeframe other than 6 months because we believe that our proposal strikes an appropriate balance among several factors: (1) the potential for fraud, waste, abuse associated with certain DME items; (2) the potential inconvenience and cost to practitioners and beneficiaries; and (3) potential health benefits to beneficiaries from increased practitioner involvement and more periodic reviews of their status and progress.

We perform ongoing education on many topics including the requirements of the other face-to-face provisions. This education includes, but is not limited to, various Medicare Learning Network® products such as MLN Matters® articles, brochures, fact sheets, Web-based training courses, and podcasts; Open Door forums; and national provider conference calls. Medicare is already working proactively with home health agencies, physicians, and other providers to educate them on implementing the face-to-face requirement. We plan to conduct similar provider education and outreach in implementing the DME face-to-face requirement.

As noted previously, section 1834(h)(3) of the Act adds prosthetic devices, orthotics, and

prosthetics to the items encompassed by section 1834(a)(11)(B) of the Act. At this time, we are not proposing changes to §410.36(b) to require documentation of a face-to-face encounter for prosthetic devices, orthotics, and prosthetics that, according to §410.36(b), require a written order before delivery in this proposed rule. We intend to use future rulemaking to determine which prosthetic devices, orthotics, and prosthetics, require, as a condition of payment, a written order before delivery supported by documentation of a face-to-face encounter with the beneficiary consistent with section 1834(a)(11)(B)(ii) of the Act. We welcome comments on including prosthetic devices, orthotics, and prosthetics in future rulemaking, including any criteria that should be used for determining what items should require a written order before delivery supported by documentation of a face-to-face encounter.

This proposed requirement does not supersede any regulatory requirements that more specifically address a face-to-face encounter requirement for a particular item of DME. For example, §410.38(c), which implemented section 1834(a)(1)(E)(iv) of the Act, specifically addresses prescription and face-to-face encounter requirements for power mobility devices (PMDs) and uses a 45-day period between the date of the face-to-face encounter and the date of the written order. That requirement is specific to the unique factors, including equipment expense and complex medical necessity determinations that affect PMDs.

(2) Physician Documentation

The statute requires that a physician document that the physician or a PA, NP or CNS has had a face-to-face encounter with the beneficiary. We propose that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record, containing sufficient information to document that the face-to-face encounter meets our requirements, would be considered sufficient and valid documentation of the face-to-face encounter when submitted to the supplier and made available to CMS or its

agents upon request. Some examples of pertinent parts of the beneficiary's medical record that can demonstrate that a face-to-face encounter has occurred can include: history; physical examination; diagnostic tests; summary of findings; diagnoses; treatment plans; or other information as appropriate. As an alternative, we are requesting comments on a second option for physicians to document the face-to-face encounter when it is performed by the physician, by requiring this physician documentation to be identical to what is required for a PA, a NP, or a CNS as discussed later in this section. We strive to find the option that strikes a balance between minimizing the effect on physicians, while still meeting the statutory objective to limit fraud, waste, and abuse.

(3) Physician Documentation of Face-to-Face Encounters Performed by a Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist

We are considering the following proposed options for physician documentation of a face-to-face encounter performed by a PA, NP, or CNS. We are reserving judgment as to which of these proposed options best accomplishes our goals until the final regulation and have not provided language reflecting these options in the proposed regulations text. The options are as follows:

- Option 1: Attestation stating: "I, Doctor (Name) (NPI number) have reviewed the medical record and attest that (PA, NP or CNS) has performed a face-to-face encounter with (beneficiary) on (date) and evaluated the need for (the item of DME)." (Sign)(Date). This option would provide all the needed information to document that a face-to-face encounter has occurred between the PA, NP or CNS and the beneficiary in a standardized manner. However, this attestation would not eliminate the need for the medical record to support the medical necessity of the ordered item. The attestation serves only as physician documentation of the face-to-face encounter.

- Option 2: The physician signs or cosigns the pertinent portion of the medical record, for the beneficiary for the date of the face-to-face encounter, thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service. This option would provide evidence that the physician has reviewed the relevant documentation to support that a face-to-face encounter occurred for that date of service. A signed order by the physician alone would not satisfy the requirement described in this option that the physician "sign/cosign the pertinent portion of the medical record."

- Option 3: The physician specifically initials the history and physical examination for the beneficiary for the date of the face-to-face encounter, thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service. This option would provide evidence that the physician has reviewed the relevant documentation to support that a face-to-face encounter occurred for that date of service. A signed order would not satisfy the requirement described in this option that the physician "initial the history and physical examination for the beneficiary for the date of the face-to-face encounter".

We welcome comment on how physician documentation requirements should be handled when the face-to-face encounter with the beneficiary is conducted by a PA, a NP, or a CNS. We are looking for the alternative that best accomplishes the objective of reducing waste, fraud, and abuse by having a physician document the face-to-face encounter if it is performed by a PA, NP, or CNS without creating undue impact.

(4) Supplier Notification

Since the supplier submits the claims for the covered items of DME, the supplier must have access to the documentation of the face-to-face encounter. We welcome comment on the type of communication that should occur between the physician or PA, NP, or CNS, and the

supplier. All documentation to support the appropriateness of the item of DME ordered including documentation of the face-to-face encounter, must be available to the supplier. As with all items and services, we require both the ordering practitioner and the supplier to maintain access to the written order and supporting documentation relating to written orders for covered items of DME and provide them to us upon our request or at the request of our contractors.

We are considering adding one of the following proposed options on how documentation of the face-to-face encounter must be delivered to the supplier. We are reserving judgment on these proposed options until the final regulation. The options are as follows:

- Option 1: Require the practitioner who wrote the order to provide the physician documentation of the face-to-face encounter directly to the DME supplier. This option may increase practitioner accountability, since it requires practitioners to submit the required documentation to the supplier.

- Option 2: Require the physician who completes the documentation of the face-to-face encounter to provide that documentation directly to the DME supplier. This option is consistent with current policies where the entity who submits the claims collects the necessary documentation even if it comes from multiple sources. For example, the supplier must have access to all documentation necessary to support the claim upon request.

- Option 3: Require that the documentation, no matter who completes it, be provided to the DME supplier through the same process as the written order for the covered item of DME. The option ensures that the same pathway followed for the order is also followed for the face-to-face documentation. In most circumstances, we would expect the order and the face-to-face documentation to travel together, the exception being those circumstances where the face-to-face encounter was conducted after the order.

- Option 4: Require a physician to provide a copy of the face-to-face documentation to the beneficiary for the beneficiary to deliver to the DME supplier of his or her choice. This would ensure that the supplier receives the documentation of the face-to-face encounter directly and limits the supplier's need to rely on the PA, NP, or CNS to receive this documentation completed by the physician.

We welcome comment on these options in order to facilitate open communication and enhanced coordination of documentation of a face-to-face encounter between the supplier, physician or when applicable, the PA, NP or CNS.

b. Covered Items

Section 1834(a)(11)(B)(i) of the Act (as redesignated by the Affordable Care Act authorizes us to specify covered items that require a written order prior to delivery of the item. Under section 1834(a)(11)(B)(ii) of the Act, these orders must be written pursuant to a physician documenting that a face-to-face encounter has occurred. Accordingly, to reduce the risk of fraud, waste, and abuse, we are proposing a list of Specified Covered Items that would require a written order prior to delivery. Our proposed list of Specified Covered Items is below. In future years, updates to this list would appear annually in the **Federal Register** and the full updated list would be available on the CMS Website.

As highlighted in the January 2007 Government Accountability Office (GAO) report entitled, "Improvements Needed to Address Improper Payments for Medical Equipment and Supplies" it is estimated that there were $700 million in improper payments across the spectrum of DMEPOS from April 1, 2005, through March 31, 2006. GAO did not specifically recommend the use of DME face-to-face encounters as a remedial action in its report. However, the GAO did recommend making improvements to address improper payments in the DMEPOS arena. This proposed rule is one way in which we are working to prevent improper payments.

Though we initially considered making all items encompassed by section 1834(a)(11)(B) of the Act (including prosthetic and orthotic items described in section 1834(h)(3) of the Act) subject to a face-to-face encounter requirement, we have first proposed a more limited criteria driven list to balance what we believe to be broad statutory intent to establish a face-to-face requirement to prevent waste, fraud, and abuse with concerns that including all items could have an undue negative effect on practitioners and suppliers. We welcome comment on limiting the associated burden of this proposed rule by refining the number of items subject to a face-to-face encounter, while still protecting the Medicare Trust Funds.

In this section of the proposed rule, we describe our proposed criteria, as well as the reasons we selected these criteria. We first note that our proposed list of Specified Covered Items contains DME items only. We intend to use future rulemaking to apply section 1834(a)(11)(B)(ii) of the Act to prosthetics and orthotics. We believe that our proposed current focus on DME items is an appropriate way of balancing our goals of reducing waste, fraud, and abuse and limiting burden on beneficiaries and the supplier community.

We propose to focus initially on DME items for several reasons. First, these items are often marketed directly to beneficiaries and requiring a face-to-face encounter would help ensure that a practitioner has met with the beneficiary and considered whether the item is appropriate. Additionally, requiring a face-to-face encounter would help ensure that practitioners who order DME items are familiar with the beneficiary's medical condition, that this condition is documented, and that the item is reasonable and necessary. Although we are also concerned about fraud, waste, and abuse associated with prosthetics and prosthetic devices, these items are, as stated in the Medicare Claims Processing Manual Chapter 20 (Section 10.1.2) "devices that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ." The body member that is being replaced by

the prosthetic device can often be identified based on previous claims history. We will consider this separately as there may be different burden issues and other considerations that apply. Therefore we are not pursuing a face-to-face requirement on these items at this time. Further, since orthotics are treated in a manner similar to prosthetics for billing and coverage purposes, in order to apply consistent criteria these items will be considered together for future rulemaking.

We welcome comment on limiting the associated burden of this proposed regulation by refining the number of items subject to a face-to-face encounter, while still protecting the Medicare Trust Funds and also meeting the requirements of the statute.

The proposed list of Specified Covered Items contains items that meet at least one of the following four criteria: (1) items that currently require a written order prior to delivery per instructions in our Program Integrity Manual; (2) items that cost more than $1,000; (3) items that we, based on our experience and recommendations from the DME MACs, believe are particularly susceptible to fraud, waste, and abuse; (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the HHS Office of Inspector General, Government Accountability Office or other oversight entities.

We are proposing to include items already listed in the Program Integrity Manual (PIM), Chapter 5, section 5.2.3.1. These items were added to the PIM originally since they were seen as posing vulnerabilities to the Medicare program that could be mitigated through requiring a written order prior to delivery. We believe that requiring a face-to-face encounter is consistent with our previous initiatives and strengthens our efforts to address this vulnerability.

We are also proposing to include any items of DME with a price ceiling greater than or equal to $1,000 in the price ceiling column on the DMEPOS Fee Schedule, which is updated annually and lists Medicare allowable pricing for DME. We believe that improper claims related to these high dollar items have a greater effect on the Medicare Trust Funds based on amounts

paid by Medicare for these items. Therefore, any items that are $1,000 or greater would be added annually to the list of Specified Covered Items on a prospective basis. For administrative simplicity we would not annually adjust this value for inflation, any changes to this threshold will go through rulemaking. We see this price point as striking a balance between our responsibility to protect the Medicare Trust Funds and ensuring these requirements do not place an additional burden on beneficiaries, practitioners, and suppliers. Our objective is to minimize inappropriate use of high dollar DME items to help protect and preserve the Medicare Trust Funds.

The third criterion added items that we believe, based on our experience and recommendations from our DME Medicare MACs are particularly susceptible to fraud, waste, and abuse. Based on their experience, the DME MACs suggested items that warrant increased practitioner involvement because these items are often marketed directly to beneficiaries, thus highlighting the important role of the practitioner in conducting a needs assessment, evaluating, or treating the beneficiary to ensure that his/her condition warrants the item. The evaluations may assist in ensuring that the DME items are medically necessary for the beneficiary. Increasing the practitioner's role in evaluating the beneficiary's need for such items, would help ensure proper ordering of DME items, thereby minimizing the risk of waste, fraud, and abuse. The items recommended by the DME contractors were pressure reducing pads, mattress overlays, mattress, beds, seat lift mechanisms, TENS units, AEDs, external infusion pumps, glucose monitors, wheelchairs and wheelchair accessories, nebulizers, negative pressure wound therapy pumps, oxygen and oxygen equipment, pneumatic compression devices, positive airway pressure devices, respiratory assists devices, and cervical traction devices.

This criterion was also influenced by our experience with the Health Care Fraud and Prevention and Enforcement Action Teams (HEAT). These teams were established by HHS and

the Department of Justice (DOJ) to investigate, among other things, fraudulent DME suppliers and have recovered millions of dollars in DME fraud. The HEAT strike force teams, which are now in nine cities nationwide, have assisted in investigating and prosecuting DME suppliers who were fraudulently seeking payment for DME items and services. HEAT investigations have resulted in indictments against DME suppliers relating to the following items: pressure reducing mattresses, oxygen equipment, manual wheelchairs, hospital beds, infusion supplies, and nebulizers. Further information about DME fraud by State is available at www.stopmedicarefraud.gov.

We are also proposing the inclusion of certain items of DME on the list of Specified Covered Items because OIG has expressed concerns (as expressed in DHHS-OIG reports since 1999) that these items are vulnerable to fraud, waste and abuse. These reports detailed vulnerabilities and called for CMS to address these issues. For example, in an OIG Report entitled "Inappropriate Medicare Payments for Pressure Reducing Support Surfaces" (OEI-02-07-00420), the OIG noted as a vulnerability the fact that the vast majority of pressure reducing pads that were billed failed to meet the coverage criteria. Home oxygen therapy was highlighted as a vulnerability in the OIG Report entitled "Usage and Documentation of Home Oxygen Therapy" (OEI-03-96-00090). Documentation and communication problems associated with negative pressure wound therapy pumps were highlighted in a report titled "Comparison of Prices for Negative Pressure Wound Therapy Pumps" (OEI-02-07-00660). As the OIG explained in that report, " [s]uppliers are required to communicate with the beneficiary's treating clinician to assess wound healing progress and to determine whether the beneficiary continues to qualify for Medicare coverage of the pump . . . [S]uppliers reported not having contact with clinicians for almost one-quarter of the beneficiaries. "

Our proposed list of Specified Covered Items is in Table 24 of this proposed rule. We

further propose to update this list of Specified Covered Items annually in order to add any new items that are described by a *HCPCS* code for the following types of DME:

- TENS unit
- Rollabout chair
- Manual Wheelchair accessories
- Oxygen and respiratory equipment
- Hospital beds and accessories
- Traction-cervical

Note that the proposed list does not include power mobility devices, which are subject to already existing face-to-face requirements, as previously discussed. In addition, we propose to add to the list any item of DME that in the future appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000. Items not included in one of the proposed automatic pathways would be added to the list of Specified Covered Items through notice and comment rulemaking.

Through updates in the **Federal Register**, we propose removing *HCPCS codes from the list* that are no longer covered by Medicare or that are discontinued HCPCS codes.

**TABLE 24: DME List of Specified Covered Items**

| HCPCS Code | Description |
|---|---|
| E0185 | Gel or gel-like pressure mattress pad |
| E0188 | Synthetic sheepskin pad |
| E0189 | Lamb's wool sheepskin pad |
| E0194 | Air fluidized bed |
| E0197 | Air pressure pad for mattress standard length and width |
| E0198 | Water pressure pad for mattress standard length and width |
| E0199 | Dry pressure pad for mattress standard length and width |
| E0250 | Hospital bed fixed height with any type of side rails, mattress |
| E0251 | Hospital bed fixed height with any type side rails without mattress |
| E0255 | Hospital bed variable height with any type side rails with mattress |
| E0256 | Hospital bed variable height with any type side rails without mattress |
| E0260 | Hospital bed semi-electric (Head and foot adjustment) with any type |

| HCPCS Code | Description |
|---|---|
| | side rails with mattress |
| E0261 | Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress |
| E0265 | Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress |
| E0266 | Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress |
| E0290 | Hospital bed fixed height without rails with mattress |
| E0291 | Hospital bed fixed height without rail without mattress |
| E0292 | Hospital bed variable height without rail without mattress |
| E0293 | Hospital bed variable height without rail with mattress |
| E0294 | Hospital bed semi-electric (head and foot adjustment) without rail with mattress |
| E0295 | Hospital bed semi-electric (head and foot adjustment) without rail without mattress |
| E0296 | Hospital bed total electric (head, foot and height adjustments) without rail with mattress |
| E0297 | Hospital bed total electric (head, foot and height adjustments) without rail without mattress |
| E0300 | Pediatric crib, hospital grade, fully enclosed |
| E0301 | Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress |
| E0302 | Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress |
| E0303 | Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress |
| E0304 | Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress |
| E0424 | Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing |
| E0431 | Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing |
| E0433 | Portable liquid oxygen system |
| E0434 | Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing |
| E0439 | Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing |
| E0441 | Oxygen contents, gaseous (1 months supply) |
| E0442 | Oxygen contents, liquid (1 months supply) |
| E0443 | Portable Oxygen contents, gas (1 months supply) |
| E0444 | Portable oxygen contents, liquid (1 months supply) |
| E0450 | Volume control ventilator without pressure support used with |

| HCPCS Code | Description |
|---|---|
| | invasive interface |
| E0457 | Chest shell |
| E0459 | Chest wrap |
| E0460 | Negative pressure ventilator portable or stationary |
| E0461 | Volume control ventilator without pressure support node for a noninvasive interface |
| E0462 | Rocking bed with or without side rail |
| E0463 | Pressure support ventilator with volume control mode used for invasive surfaces |
| E0464 | Pressure support vent with volume control mode used for noninvasive surfaces |
| E0470 | Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface |
| E0471 | Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface |
| E0472 | Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface |
| E0480 | Percussor electric/pneumatic home model |
| E0482 | Cough stimulating device, alternating positive and negative airway pressure |
| E0483 | High Frequency chest wall oscillation air pulse generator system |
| E0484 | Oscillatory positive expiratory device, non-electric |
| E0570 | Nebulizer with compressor |
| E0575 | Nebulizer, ultrasonic, large volume |
| E0580 | Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter |
| E0585 | Nebulizer with compressor & heater |
| E0601 | Continuous airway pressure device |
| E0607 | Home blood glucose monitor |
| E0627 | Seat lift mechanism incorporated lift-chair |
| E0628 | Separate Seat lift mechanism for patient owned furniture electric |
| E0629 | Separate seat lift mechanism for patient owned furniture non-electric |
| E0636 | Multi positional patient support system, with integrated lift, patient accessible controls |
| E0650 | Pneumatic compressor non-segmental home model |
| E0651 | Pneumatic compressor segmental home model without calibrated gradient pressure |
| E0652 | Pneumatic compressor segmental home model with calibrated gradient pressure |
| E0655 | Non- segmental pneumatic appliance for use with pneumatic compressor on half arm |
| E0656 | Non- segmental pneumatic appliance for use with pneumatic compressor on trunk |

| HCPCS Code | Description |
|---|---|
| E0657 | Non- segmental pneumatic appliance for use with pneumatic compressor chest |
| E0660 | Non- segmental pneumatic appliance for use with pneumatic compressor on full leg |
| E0665 | Non- segmental pneumatic appliance for use with pneumatic compressor on full arm |
| E0666 | Non- segmental pneumatic appliance for use with pneumatic compressor on half leg |
| E0667 | Segmental pneumatic appliance for use with pneumatic compressor on full-leg |
| E0668 | Segmental pneumatic appliance for use with pneumatic compressor on full arm |
| E0669 | Segmental pneumatic appliance for use with pneumatic compressor on half leg |
| E0671 | Segmental gradient pressure pneumatic appliance full leg |
| E0672 | Segmental gradient pressure pneumatic appliance full arm |
| E0673 | Segmental gradient pressure pneumatic appliance half leg |
| E0675 | Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency |
| E0692 | Ultraviolet light therapy system panel treatment 4 foot panel |
| E0693 | Ultraviolet light therapy system panel treatment 6 foot panel |
| E0694 | Ultraviolet multidirectional light therapy system in 6 foot cabinet |
| E0720 | Transcutaneous electrical nerve stimulation, two lead, local stimulation |
| E0730 | Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation |
| E0731 | Form fitting conductive garment for delivery of TENS or NMES |
| E0740 | Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer |
| E0744 | Neuromuscular stimulator for scoliosis |
| E0745 | Neuromuscular stimulator electric shock unit |
| E0747 | Osteogenesis stimulator, electrical, non-invasive, other than spine application. |
| E0748 | Osteogenesis stimulator, electrical, non-invasive, spinal application |
| E0749 | Osteogenesis stimulator, electrical, surgically implanted |
| E0760 | Osteogenesis stimulator, low intensity ultrasound, non-invasive |
| E0762 | Transcutaneous electrical joint stimulation system including all accessories |
| E0764 | Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls |
| E0765 | FDA approved nerve stimulator for treatment of nausea & vomiting |
| E0782 | Infusion pumps, implantable, Non-programmable |
| E0783 | Infusion pump, implantable, Programmable |
| E0784 | External ambulatory infusion pump |

| HCPCS Code | Description |
|---|---|
| E0786 | Implantable programmable infusion pump, replacement |
| E0840 | Tract frame attach to headboard, cervical traction |
| E0849 | Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible |
| E0850 | Traction stand, free standing, cervical traction |
| E0855 | Cervical traction equipment not requiring additional stand or frame |
| E0856 | Cervical traction device, cervical collar with inflatable air bladder |
| E0958 | Manual wheelchair accessory, one-arm drive attachment |
| E0959 | Manual wheelchair accessory-adapter for Amputee |
| E0960 | Manual wheelchair accessory, shoulder harness/strap |
| E0961 | Manual wheelchair accessory wheel lock brake extension handle |
| E0966 | Manual wheelchair accessory, headrest extension |
| E0967 | Manual wheelchair accessory, hand rim with projections |
| E0968 | Commode seat, wheelchair |
| E0969 | Narrowing device wheelchair |
| E0971 | Manual wheelchair accessory anti-tipping device |
| E0973 | Manual wheelchair accessory, adjustable height, detachable armrest |
| E0974 | Manual wheelchair accessory anti-rollback device |
| E0978 | Manual wheelchair accessory positioning belt/safety belt/ pelvic strap |
| E0980 | Manual wheelchair accessory safety vest |
| E0981 | Manual wheelchair accessory Seat upholstery, replacement only |
| E0982 | Manual wheelchair accessory, back upholstery, replacement only |
| E0983 | Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control |
| E0984 | Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control |
| E0985 | Wheelchair accessory, seat lift mechanism |
| E0986 | Manual wheelchair accessory, push activated power assist |
| E0990 | Manual wheelchair accessory, elevating leg rest |
| E0992 | Manual wheelchair accessory, elevating leg rest solid seat insert |
| E0994 | Arm rest |
| E0995 | Wheelchair accessory calf rest |
| E1002 | Wheelchair accessory Power seating system, tilt only |
| E1003 | Wheelchair accessory Power seating system, recline only without shear |
| E1004 | Wheelchair accessory Power seating system, recline only with mechanical shear |
| E1005 | Wheelchair accessory Power seating system, recline only with power shear |
| E1006 | Wheelchair accessory Power seating system, tilt and recline without shear |
| E1007 | Wheelchair accessory Power seating system, tilt and recline with mechanical shear |

| HCPCS Code | Description |
|---|---|
| E1008 | Wheelchair accessory Power seating system, tilt and recline with power shear |
| E1010 | Wheelchair accessory, addition to power seating system, power leg elevation system, including leg rest pair |
| E1014 | Reclining back, addition to pediatric size wheelchair |
| E1015 | Shock absorber for manual wheelchair |
| E1020 | Residual limb support system for wheelchair |
| E1028 | Wheelchair accessory, manual swing away, retractable or removable mounting hardware for joystick, other control interface or positioning accessory |
| E1029 | Wheelchair accessory, ventilator tray |
| E1030 | Wheelchair accessory, ventilator tray, gimbaled |
| E1031 | Rollabout chair, any and all types with castors 5" or greater |
| E1035 | Multi-positional patient transfer system with integrated seat operated by care giver |
| E1036 | Patient transfer system |
| E1037 | Transport chair, pediatric size |
| E1038 | Transport chair, adult size up to 300lb |
| E1039 | Transport chair, adult size heavy duty >300lb |
| E1161 | Manual Adult size wheelchair includes tilt in space |
| E1227 | Special height arm for wheelchair |
| E1228 | Special back height for wheelchair |
| E1232 | Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system |
| E1233 | Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system |
| E1234 | Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system |
| E1235 | Wheelchair, pediatric size, rigid, adjustable, with seating system |
| E1236 | Wheelchair, pediatric size, folding, adjustable, with seating system |
| E1237 | Wheelchair, pediatric size, rigid, adjustable, without seating system |
| E1238 | Wheelchair, pediatric size, folding, adjustable, without seating system |
| E1296 | Special sized wheelchair seat height |
| E1297 | Special sized wheelchair seat depth by upholstery |
| E1298 | Special sized wheelchair seat depth and/or width by construction |
| E1310 | Whirlpool non-portable |
| E2502 | Speech Generating Devices prerecord messages between 8 and 20 Minutes |
| E2506 | Speech Generating Devices prerecord messages over 40 minutes |
| E2508 | Speech Generating Devices message through spelling, manual type |
| E2510 | Speech Generating Devices synthesized with multiple message methods |

| HCPCS Code | Description |
|---|---|
| E2227 | Rigid pediatric wheelchair adjustable |
| K0001 | Standard wheelchair |
| K0002 | Standard hemi (low seat) wheelchair |
| K0003 | Lightweight wheelchair |
| K0004 | High strength ltwt wheelchair |
| K0005 | Ultra Lightweight wheelchair |
| K0006 | Heavy duty wheelchair |
| K0007 | Extra heavy duty wheelchair |
| K0009 | Other manual wheelchair/base |
| K0606 | AED garment with electronic analysis |
| K0730 | Controlled dose inhalation drug delivery system |

c. Physician Payment

We understand that there is a burden associated with the requirement placed on the physician to document that a face-to-face encounter has occurred between a PA, a NP or a CNS, and the beneficiary. Accordingly, we are proposing the introduction of a G-code, estimated at $15, to compensate a physician who documented that a PA, a NP, or a CNS practitioner has performed a face-to-face encounter for the list of specified covered items above. This G-code would become effective when this provision becomes effective. We believe that the existing Evaluation and Management (E&M) codes are sufficient for practitioners performing face-to-face encounters. This new G-code would be specifically designed and mapped only for a physician who completes the documentation of the face-to-face encounter performed by a PA, a NP, or a CNS. Only a physician who does not bill an E&M code for the beneficiary in question would be eligible for this G-code. If multiple written orders for covered items of DME originate from one visit, the physician can receive the G-code payment only once for documenting that the face-to-face encounter has occurred. The G-code would be mapped so that only eligible DME items would be covered. Upon request, we will need to see documentation of the face-to-face encounter in order to verify the appropriateness of the G-code payment.

D. Elimination of the Requirement for Termination of Non-random Prepayment Complex Medical Review (§421.500 through §421.505)

Medical review is the process performed by Medicare contractors to ensure that billed items or services are covered and are reasonable and necessary as specified under section 1862(a)(1)(A) of the Act. We enter into contractual agreements with contractors to perform medical review functions. On December 8, 2003, the Congress enacted the MMA. Section 934 of the MMA amended section 1874A of the Act by adding a new subsection (h) – regarding random prepayment reviews and non-random prepayment complex medical reviews and

requiring us to establish termination dates for non-random prepayment complex medical reviews. Although section 934 of the MMA set forth requirements for random prepayment review, our contractors do not perform random prepayment review. However, our contractors do perform non-random prepayment complex medical review.

On September 26, 2008, we published a final rule in the **Federal Register** (73 FR 55753) entitled, "Medicare Program; Termination of Non-Random Prepayment Complex Medical Review" that specified the criteria contractors would use for the termination of providers and suppliers from non-random prepayment complex medical review as required under the MMA. The final rule required contractors to terminate the non-random prepayment complex medical review of a provider or supplier no later than 1 year following the initiation of the complex medical review or when calculation of the error rate indicates the provider or supplier has reduced its initial error rate by 70 percent or more. (For more detailed information, see the September 26, 2008 final rule (73 FR 55753)).

On March 23, 2010, the Congress enacted the Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111-152) (together known as the Affordable Care Act). Section 1302 of the HCERA, repealed section 1874A(h) of the Act.

Section 1302 of the HCERA repealed section 1874A (h) of the Act, and therefore, removed the statutory basis for our regulation. Thus, we propose to remove the regulatory provisions in 42 CFR part 421, subpart F, that require contractors to terminate a provider or supplier from non-random prepayment complex medical review no later than 1 year following the initiation of the medical review or when the provider or supplier has reduced its initial error rate by 70 percent or more. As a result of this proposal, contractors would not be required to terminate non-random prepayment medical review by a prescribed time but would instead

terminate each medical review when the provider or supplier has met all Medicare billing requirements as evidenced by an acceptable error rate as determined by the contractor.

E. Ambulance Coverage-Physician Certification Statement

We propose to revise §410.40(d)(2) by incorporating nearly the same provision found at §410.40(d)(3)(v) to clarify that a physician certification statement (PCS) does not, in and of itself, demonstrate that a nonemergency, scheduled, repetitive ambulance service is medically necessary for Medicare coverage. The Medicare ambulance benefit at section 1861(s)(7) of the Act allows for "ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but. . . only to the extent provided in regulations." In other words, the definition of the benefit itself embodies the clinical medical necessity requirement that other forms of transportation must be contraindicated by a beneficiary's condition. Section 410.40(d) interprets the medical necessity requirement. Notably, even aside from the requirements of section 1861(s)(7), section 1862(a)(1)(A) of the Act dictates that any service that is not medically necessary under the Act and regulations is not a covered benefit.

Despite these statutory provisions and the language of the present regulation at section 410.40(d)(2) that we believe already requires both medical necessity and a PCS, some courts have recently concluded that §410.40(d)(2) establishes that a sufficiently detailed and timely order from a beneficiary's physician, to the exclusion of any other medical necessity requirements, conclusively demonstrates medical necessity with respect to nonemergency, scheduled, repetitive ambulance services.

Absent explicit statutorily-based exceptions, we have consistently maintained that the Secretary is the final arbiter of whether a service is reasonable and necessary and qualifies for Medicare coverage. For example, in HCFA Ruling 93-1, we said "[i]t is HCFA's ruling that no presumptive weight should be assigned to the treating physician's medical opinion in

determining the medical necessity of inpatient hospital or SNF services under section 1862(a)(1) of the Act. A physician's opinion will be evaluated in the context of the evidence in the complete administrative record. Even though a physician's certification is required for payment, coverage decisions are not made based solely on this certification; they are made based on objective medical information about the patient's condition and the services received. This information is available from the claims form and, when necessary, the medical record which includes the physician's certification."

Medical necessity is not just an integral requirement of Medicare's ambulance benefit in particular, but as we mentioned, section 1862(a)(1)(A) of the Act dictates that services must be reasonable and necessary to qualify for any Medicare coverage. Numerous U.S. Circuit Courts of Appeal have held that PCSs or certificates of medical necessity do not, in and of themselves, conclusively demonstrate medical necessity. The same applies in the context of nonemergency, scheduled, repetitive ambulance services—the PCS is not, in and of itself, the sole determinant of medical necessity, and, as we discuss below, we believe the existing regulation at §410.40(d)(2) already demonstrates that. To erase any doubt, however, we propose a revision to §410.40(d)(2) to explicitly clarify this principle.

Since being finalized in the February 27, 2002 **Federal Register** (67 FR 9100, 9132), §410.40(d)(2) has stated that "Medicare covers <u>medically necessary</u> nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met." (emphasis added). Although a physician certifies with respect to medical necessity, the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. Indeed, the phrase "medically necessary" would have been surplus had we intended the PCS to be the sole

determinant of medical necessity. Rather, as demonstrated by the fact that we did include that phrase, and by various other clarifying points, we made clear that a PCS, while necessary, does not on its own conclusively demonstrate the medical necessity of nonemergency, scheduled, repetitive ambulance services.

The preamble to the February 27, 2002 final rule (Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency ambulance Services (67 FR 9100)) and the 1999 final rule with comment (FRC) (Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements (64 FR 3637)) support this interpretation.

For example, in describing comments regarding medical necessity and physician certification in the 1999 FRC, we said: "[t]wo ambulance suppliers commented that physicians are unaware of the coverage requirements for ambulance services and that their decisions to request ambulance services may be based on 'family preference or the inability to safely transport the beneficiary by other means rather than on the medical necessity requirement imposed by Medicare.'" We responded that section 1861(s)(7) of the Act allows coverage only under certain limited circumstances, and suggested that "[t]o facilitate awareness of the Medicare rules as they relate to the ambulance service benefit, ambulance suppliers may need to educate the physician (or the physician's staff members) when making arrangements for the ambulance transportation of a beneficiary." We continued that "[s]uppliers may wish to furnish an explanation of applicable medical necessity requirements, as well as requirements for physician certification, and to explain that the certification statement should indicate that the ambulance services being requested by the attending physician are medically necessary." (76 FR 3637, 3641) In light of our acknowledging a significant program vulnerability – that the physicians writing PCSs might not be fully cognizant of the Medicare ambulance benefit's medical

necessity requirements – and encouraging suppliers themselves to help remedy that by educating physicians, it would have been irrational of us to (and we did not) abrogate the Secretary's judgment and vest exclusively in the PCS the authority to demonstrate an ambulance transport's medical necessity. We made a similar point in response to a separate comment: "It is always the responsibility of the ambulance supplier to furnish complete and accurate documentation to demonstrate that the ambulance service being furnished meets the medical necessity criteria." (76 FR 3637, 3639).

In the section of the February 27, 2002 final rule preamble describing the PCS requirements, we said: "[i]n all cases, the appropriate documentation must be kept on file and, upon request, presented to the carrier or intermediary. It is important to note that the presence of the signed physician certification statement does not necessarily demonstrate that the transport was medically necessary. The ambulance supplier must meet all coverage criteria for payment to be made." (67 FR 9100, 9111). Although we incorporated that passage into the final rule only at §410.40(d)(3)(v), we intended, and we believe our intent is clear from the preamble narrative, that the principle apply equally to all nonemergency ambulance transports.

The OIG report titled "Medicare Payments for Ambulance Transports" (OEI-05-02-00590) (January 2006) also supports our position. Based on its analysis of a sample of calendar year 2002 claims, the OIG reported that "27 percent of ambulance transports to or from dialysis facilities did not meet Medicare's coverage criteria." The OIG added "the ongoing and repetitive nature of dialysis treatment makes transports to and from such treatment vulnerable to abuse. Although the condition of some patients warrants repetitive, scheduled ambulance transports for dialysis treatment, many dialysis transports do not meet coverage criteria." The OIG recommended that we instruct our contractors to implement prepayment edits with respect to dialysis transports and have them request wide-ranging documents when conducting

postpayment medical review. The fact that we agreed with the OIG's recommendations demonstrated our belief that the PCS was not the sole determinant of medical necessity. Likewise, the fact that the OIG mentioned our ambulance coverage regulations, including the PCS requirement, but did not recommend altering or clarifying the regulations with respect to medical necessity demonstrated that we were of like mind; that, while a physician certifies with respect to medical necessity, the Secretary is the final arbiter of whether a service is medically necessary.

Accordingly, we propose to revise §410.40(d)(2) to add nearly the same provision presently found at §410.40(d)(3)(v), except without reference to a "signed return receipt" that does not pertain to nonemergency, scheduled, repetitive ambulance services. We propose to accomplish this by redesignating the current language as §410.40(d)(2)(i), and adding the clarifying language to a new §410.40(d)(2)(ii). The proposed §410.40(d)(2)(ii) clarifies that a signed physician certification statement does not, in and of itself, demonstrate that an ambulance transport was reasonable and necessary. Rather, for all ambulance services, providers and suppliers must retain on file all appropriate documentation and present such documentation upon request to a Medicare contractor. A CMS contractor may use such documentation to assess, among other things, whether the service satisfied Medicare's medical necessity, eligibility, coverage, benefit category, or any other criteria necessary for Medicare payment to be made. For example, the patient's condition must be such that other means of transportation would be contraindicated, and the expenses incurred must be reasonable and necessary for the diagnosis or treatment of illness or injury.

We also propose to fix the typographical error "fro," which should be "from" in the existing § 410.40(c)(3)(ii).

F. Physician Compare Website

1. Background and Statutory Authority

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

We launched the first phase of the Physician Compare Internet website (http://www.medicare.gov/find-a-doctor/provider-search.aspx) on December 30, 2010. This initial phase included the posting of the names of eligible professionals that satisfactorily submitted quality data for the 2009 Physician Quality Reporting System, consistent with section 1848(m)(5)(G) of the Act. Since the initial launch of the website, we have continued to build and improve Physician Compare. Currently users can search by selecting a location and specialty for physicians or other healthcare professionals. Search results provide basic information about approved Medicare providers, such as primary and secondary specialties, practice locations, group practice affiliations, hospital affiliations, Medicare Assignment, education, languages spoken, and gender. As required by section 1848(m)(5)(G) of the Act, we have added the names of those eligible professionals who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. As such, physician and other healthcare professional profile pages indicate if professionals satisfactorily participated in the Physician Quality Reporting System and/or are successful electronic prescribers under the eRx Incentive Program based on the most recent data available for these two quality initiatives.

2. Public Reporting of Physician Performance

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 quality and patient experience measures. This plan is outlined below. To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System.
- 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.
- 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 seek to accomplish through rulemaking and focus groups. 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.

We are required, under section 10331(f) of the Affordable Care Act, to submit a report to the Congress by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information to make informed decisions about their

health care, 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 the Physician Compare website to publicly report physician performance results.

In implementing our plan to publicly report physician performance, we will use data reported under the existing Physician Quality Reporting System as an initial step for making physician "measure performance" information public on Physician Compare. By "measure performance" in relation to the Physician Quality Reporting System, we mean the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure. For measures requiring risk adjustment, "measure performance" refers to the risk adjusted percentage of times a particular outcome was attained.

We previously finalized a decision to make public on Physician Compare the performance rates of the quality measures that group practices submit under the 2012 Physician Quality Reporting System group practice reporting option (GPRO) (76 FR 73417). Therefore, we anticipate, no earlier than 2013, posting performance information collected through the GPRO web interface for group practices participating in the Physician Quality Reporting System GPRO CY 2012 on Physician Compare. Specifically, we will make public performance information for measures included in the 2012 Physician Quality Reporting System that meet the minimum sample size, and that prove to be statistically valid and reliable. 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 for that measure will be suppressed and not publicly reported. We previously established a minimum threshold of 25 patients for reporting performance information on the Physician Compare website (76 FR 73418). Although we considered keeping the threshold for reporting

performance data on Physician Compare at 25 patients, we propose to change the minimum patient sample size, from 25 patients to 20 patients, beginning with data collected for services furnished in 2013, to align with the proposed minimum patient reporting thresholds for Physician Quality Reporting System measures group reporting for the 2013 and 2014 incentives, and the proposed reliability thresholds for the physician value-based payment modifier. We invite comment on the proposed new minimum patient sample size for Physician Compare, including whether or not we should retain the existing threshold of 25 patients.

Furthermore, in the Shared Savings Program final rule (76 FR 67948) as codified at §425.308, we finalized ACO public reporting provisions in the interest of promoting greater transparency regarding the ACOs participating in the program. We finalized requirements for ACOs to publicly report certain data as well as data that we would publicly report. Because ACO providers/suppliers that are eligible professionals are considered to be group practices for purposes of qualifying for a Physician Quality Reporting System incentive under the Shared Savings Program, we indicated that performance on quality measures reported by ACOs at the ACO TIN level, on behalf of their ACO providers/suppliers who are eligible professionals, using the GPRO web interface would be reported on Physician Compare in the same way as for the groups that report under the Physician Quality Reporting System.

In April 2012, we added functionality to Physician Compare allowing users to search for group practices in preparation for the addition of 2012 Physician Quality Reporting System GPRO data. A full website redesign is slated for early 2013 to further prepare the site for the introduction of quality data. With each enhancement, we work to improve the usability and functionality of the site, providing consumers with more tools to help them make informed healthcare decisions.

In CY 2012, we intend to enhance the accuracy of “administrative” information displayed

on the eligible professional's profile page, and to add additional data. By "administrative" data, we are referring to information about eligible professionals that is pulled from the Provider Enrollment, Chain, and Ownership System (PECOS) and other readily available external data sources. Specifically, we intend to add whether a physician/other health care professional is accepting new Medicare patients, board certification information, and to improve the foreign language and hospital affiliation data. We also intend to include the names of those eligible professionals who participated in the Medicare EHR Incentive Program and the names of those eligible professionals who satisfactorily participated under the Physician Quality Reporting System GPRO. We will continue to update the names of those eligible professionals and group practices who satisfactorily participated under the Physician Quality Reporting System, and those who are successful electronic prescribers under the eRx Incentive Program based on the most recent program year data available.

In support of the HHS-wide Million Hearts Initiative, we propose to post the names of the eligible professionals who report the Physician Quality Reporting System Cardiovascular Prevention measures group. This is consistent with the requirements under section 10331 of the Affordable Care Act to provide information about physicians and other eligible professionals who participate in the Physician Quality Reporting System.

3. Future Development of Physician Compare

Consistent with Affordable Care Act requirements, we intend to phase in an expansion of Physician Compare over the next several years by incorporating quality measures from a variety of sources, if technically feasible. For our next phase, we propose to make public on Physician Compare, performance rates on the quality measures that group practices submit through the GPRO web interface under the 2013 Physician Quality Reporting System GPRO and the Medicare Shared Savings Program. We anticipate that the 2013 Physician Quality Reporting

System GPRO web interface measures data would be posted no sooner than 2014. This data would include measure performance rates for measures included in the 2013 Physician Quality Reporting System GPRO web interface that meet the proposed minimum sample size of 20 patients, and that prove to be statistically valid and reliable.

When technically feasible, but no earlier than 2014, we propose to publicly report composite measures that reflect group performance across several related measures. As an initial step we intend to develop disease module level composite scores for Physician Quality Reporting System GPRO measures. Under the Medicare Shared Savings Program, ACOs are required to report on composite measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) (76 FR 67891). Accordingly, in an effort to align the PQRS GPRO measures with the GPRO measures under the Shared Savings Program, we have proposed in Table 35 of this proposed rule to add composite measures for DM and CAD into the Physician Quality Reporting System starting in 2013. We will also consider future development of composites for the remaining disease level modules within the GPRO web interface. As more data are added to Physician Compare over time, we will consider adding additional disease level composites across measure types as technically feasible and statistically valid.

Consistent with the requirement under section 10331(a)(2) under the Affordable Care Act to implement a plan to make publically available comparable information on patient experience of care measures, we propose to add patient experience survey-based measures such as, but not limited to, the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS). As discussed in section G.6.c. of this proposed rule, we propose to collect the following patient experience of care measures for group practices participating in the Physician Quality Reporting System GPRO;

- 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 propose, no earlier than 2014, to publicly report 2013 patient experience data for all group practices participating in the 2013 Physician Quality Reporting System GPRO, not limited to those groups participating via the GPRO web interface, on Physician Compare. At least for 2013, we intend to administer and collect patient experience survey data on a sample of the group practices' beneficiaries. As we intend to administer and collect the data for these surveys, we do not anticipate any notable burden on the groups.

For ACOs participating in the Shared Savings Program, consistent with the Physician Quality Reporting System proposal to publicly report patient experience measures on Physician Compare starting in 2013, we propose to publicly report patient experience data in addition to the measure data reported through the GPRO web interface. Specifically, the patient experience measures that would be reported for ACOs include the 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

For patient experience data reported under either the Physician Quality Reporting System GPRO or the Medicare Shared Savings Program, we also considered an alternative option of providing confidential feedback to group practices and ACOs using 2013 patient experience data before publicly reporting patient experience data on Physician Compare. In lieu of publicly reporting the patient experience data relating to 2013 Physician Quality Reporting System GPRO and ACOs participating in the Shared Savings Program, we considered using the 2013 results as a baseline to be shared confidentially with the group practices and ACOs, during which time the group practices and ACOs would have the opportunity to review their data, and implement changes to improve patient experience scores. Under this alternative option, program year 2014 patient experience data would be the first to be publicly reported on Physician Compare, and we would publicly report 2014 patient experience data for ACOs and group practices participating in the 2014 Physician Quality Reporting System GPRO on Physician Compare no earlier than 2015. We invite public comment on our proposal to begin publicly reporting patient experience data for program year 2013, and also the alternative option of delaying public reporting of patient experience of care data on Physician Compare until program year 2014 in order to give group practices and ACOs the opportunity to make changes to the processes used in their practices based on the review of their data from program year 2013.

As we continue to improve administrative and provider level data, we propose posting the names of those physicians who earned a Physician Quality Reporting System Maintenance of Certification Program incentive as data becomes available, but no sooner than 2014. Additionally, we are considering allowing measures that have been developed and collected by approved and vetted specialty societies to be reported on Physician Compare, as deemed appropriate, and as they are found to be scientifically sound and statistically valid. We propose including additional claims-based process, outcome and resource use measures on Physician

Compare, and intend to align measure selection for Physician Compare with measures selected for the Value Based Modifier (section III.K).

As an initial step, we propose to include group level ambulatory care sensitive condition admission measures of potentially preventable hospitalizations developed by the HHS Agency for Healthcare Research and Quality (AHRQ) that meet the proposed minimum sample size of 20 patients, and that prove to be statistically valid and reliable (measure details are available at http://www.qualitymeasures.ahrq.gov/content.aspx?id=27275). We propose reporting these measures on Physician Compare no earlier than 2015 for those group practices comprised of 2 - 99 eligible professionals participating in the proposed 2014 physician Quality Reporting System GPRO, and for ACOs. As our next step, we propose to publicly report performance rates on quality measures included in the 2015 Physician Quality Reporting System and value-based payment modifier for individual eligible professionals. Further details on what measures would be included in the 2015 reporting period will be addressed in future rule making. Public reporting of 2015 PQRS and administrative claims-based quality measures for individuals would occur no earlier than 2016. For all measures publicly reported on the Physician Compare website, we propose to post a standard of care, such as those endorsed by the National Quality Forum. Such information will serve as a standard for consumers to measure individual provider, and group level data.

We are committed to making Physician Compare a constructive tool for Medicare beneficiaries, successfully meeting the Affordable Care Act mandate, and in doing so, providing consumers with information needed to make informed healthcare decisions. CMS has developed a plan, and started to implement a phased approach to adding quality data to Physician Compare. We believe a staged approach to public reporting of physician information allows for the use of information currently available while we develop the infrastructure necessary to support the

collection of additional types of measures and public reporting of individual physicians' quality measure performance results. Implementation of subsequent phases of the plan will need to be developed and addressed in future notice and comment rulemaking, as needed.

We invite comments regarding our proposals to: (1) reduce the minimum reporting threshold from 25 patients to 20 patients for reporting on Physician Compare; (2) post the names of the eligible professionals who report the Physician Quality Reporting System Cardiovascular Prevention measures group for purposes of recognition and in support of the Million Hearts Initiative; (3) develop composite measures at the disease module level, initially with CY 2013 GPRO data, and incorporating additional measures; (4) to publicly report 2013 patient experience data for group practices participating in the 2013 Physician Quality Reporting System GPRO, or who are part of an ACO under the Medicare Shared Savings Program, on the Physician Compare website no earlier than 2014; (5) the alternative option of providing confidential feedback to group practices and ACOs on 2013 patient experience data to allow them to make necessary changes to their processes prior to publicly reporting of 2014 patient experience data on Physician Compare; (6) report names of participants who earn a 2013 Physician Quality Reporting System Maintenance of Certification Program Incentive no earlier than 2014; (7) allow measures that have been developed and collected by specialty societies to be reported on the Physician Compare website as deemed appropriate; (8) to report 2014 group level ambulatory care sensitive condition measures of potentially preventable hospitalizations developed by the AHRQ no earlier than 2015 for groups participating in the 2014 Physician Quality Reporting System and ACOs, (measure details are available at http://www.qualitymeasures.ahrq.gov/content.aspx?id=27275); (9) publicly report performance on 2015 Physician Quality Reporting System and value-based payment modifier quality measures for individuals. Public reporting of 2015 Physician Quality Reporting System and

claims derived quality measures for individuals would occur no earlier than 2016; and (10) post a standard of care for measures posted on Physician Compare. For the above proposals, we note that we would only post data on Physician Compare if it is technically feasible; the data is available; the system is set up/adjusted to post information and the data is useful, sufficiently reliable, and accurate.

G. 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. The National Quality Strategy establishes three aims for quality improvement across the nation: better health, better healthcare, and lower costs. This strategy, the first of its kind, outlines a national vision for quality improvement and creates an opportunity for programs to align quality measurement and incentives across the continuum of care. CMS believes that this alignment is especially critical for programs involving physicians. The proposals that follow facilitate the alignment of programs, reporting systems, and quality measures to make this vision a reality. 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. CMS believes, however, that in order to improve quality, physicians must first engage in quality measurement and reporting. It is CMS's intent that the following proposals will improve alignment of physician-focused quality improvement programs, decrease the burden of successful participation on physicians, increase engagement of physicians in quality improvement, and ultimately lead to higher quality care for beneficiaries.

This section contains our proposals related to the Physician Quality Reporting System (PQRS). The PQRS, as set forth in section 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments and payment adjustments to eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. We note that, in developing these proposals, it was our goal to align program requirements between these quality reporting programs, such as the eRx

Incentive Program, EHR Incentive Program, Medicare Shared Savings Program, and value-based payment modifier, wherever possible. We believe that alignment of these quality reporting programs will lead to greater overall participation in these programs, as well as minimize the reporting burden on eligible professionals.

For example, we have aligned the definition of group practice under the eRx Incentive Program with PQRS' definition of group practice. Our proposals with respect to reporting as a group practice for the eRx Incentive Program are intended to conform to our proposals for reporting as a group practice for PQRS.

With respect to integration with the EHR Incentive Program, section 1848(m)(7) of the Act requires us to develop a plan to integrate reporting on quality measures under the PQRS with reporting requirements under the EHR Incentive Program. We began integrating requirements for these two programs in 2012 with the alignment of reporting requirements via the Physician Quality Reporting System-Medicare EHR Incentive Pilot (76 FR 73422) and the alignment of reportable EHR measures (76 FR 73364). Our proposals in this section are intended to move the PQRS and EHR Incentive Program towards greater alignment, benefiting those eligible professionals who wish to participate in both programs. The vision is to report once for multiple programs on a set of measures aligned across programs and with the National Quality Strategy.

With respect to integration with the value-based payment modifier, we note that we began our efforts to integrate our program requirements with the value-based payment modifier in the CY 2012 Medicare PFS final rule, when CY 2013 was established as the reporting period for the 2015 PQRS payment adjustment (76 FR 73391) and the initial performance period for the application of the value modifier (76 FR 73435). Our proposals in this section, particularly as they relate to the proposed requirements for satisfactory reporting for the PQRS payment adjustments, are intended to align with the proposals for the application of the value modifier.

The regulation governing the PQRS is located at §414.90. The program requirements for years 2007-2012 of the PQRS that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html. Please also note that in this proposed rule, we are proposing to make technical changes to §414.90 to aid in the readability of the regulation.

1. Methods of Participation

There are two ways an eligible professional can participate in the PQRS: (1) as in individual or (2) as part of a group practice participating in the PQRS group practice reporting option (GPRO).

a. Participation as an Individual Eligible Professional

(1) Participation for the 2013 and 2014 Incentives

As defined at §414.90(b) the term ''eligible professional'' means any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist. For more information on which professionals are eligible to participate in the Physician Quality Reporting System, we refer readers to the ''List of Eligible Professionals'' download located in the ''How to Get Started" section of the PQRS CMS Website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/How_To_Get_Started.html. There is no requirement to self-nominate to participate in PQRS as an individual eligible professional for the incentive or to use the claims, registry, or EHR reporting mechanisms.

(2) Proposed Requirement for Eligible Professionals and Group Practices Electing to Use the Administrative Claims-based Reporting Mechanism for the 2015 and 2016 Payment Adjustments

Unlike using the traditional PQRS reporting mechanisms (claims, registry, EHRs) to satisfy the reporting requirements for the 2015 and 2016 payment adjustments, we propose that eligible professionals and group practices wishing to use the administrative claims reporting mechanism, which is discussed in section K, and available for the 2015 and/or 2016 payment adjustments, must elect to use the administrative claims reporting mechanism (please note that since the same proposed requirements would apply to both individual eligible professionals and group practices, we address both in this discussion). We believe this election requirement is necessary because CMS must be notified that CMS must analyze and calculate data from an eligible professional or group practice's claims. This election requirement is not necessary for eligible professionals and group practices using traditional PQRS reporting mechanisms because, for these traditional reporting mechanisms, CMS is not involved with analyzing claims data to determine whether a clinical quality action related to a quality measure was performed.

For eligible professionals, we propose that this election process would consist of a registration statement that includes: the eligible professional's name and practice name, the eligible professional's TIN and NPI for analytical purposes, and the eligible professional's contact information. For group practices, we propose that this election process would also consist of a registration statement that includes: the group practice's business name and contact information, the group practice's TIN, and contact information of the group practice's contact(s) who will be contacted for program, clinical, and/or technical purposes. With respect to the method of submitting this registration statement, we propose the following options:

- If technically feasible, submission of this statement via the web and
- If technically feasible, submission of an eligible professional's or group practice's intent to register to use the administrative claims-based reporting mechanism by placing a G-code on at least 1 Medicare Part B claim.

In the event the two proposed options are not technically feasible, we also considered allowing for submission of the registration statement by submitting a mailed letter to CMS at Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-1850a. However, we note that using this mailing option would be a more burdensome and time-intensive process for CMS. We invite public comment on this considered option.

The eligible professional would be required to complete this election process by January 31 of the applicable payment adjustment reporting period (for example, by January 31, 2015 for the 2015 payment adjustment). However, we note that we propose that we may extend this deadline based on the submission method that is finalized. For example, because processing mailed letters would take the longest to process (out of the 3 methods), we anticipate that if we were to include the option of mailed letters the deadline for submitting a mailed registration letter would be January 31 of the applicable payment adjustment reporting period. Since it would be more efficient to process registration statements received via the web or via a G-code on a claim, we anticipate that we would be able to extend the registration deadline to as late as December 31 of the applicable payment adjustment reporting period. Once an eligible professional makes an election to participate in PQRS using the administrative claims-based reporting mechanism for the PQRS payment adjustments, the eligible professional would be assessed under the administrative claims-based reporting mechanism.

For group practices participating in the GPRO, we propose that these group practices would use the 2 methods described above (mailed letter, web, or G-code submission) and have the same deadline as eligible professionals wishing to elect to use the administrative claims-based reporting mechanism for an applicable payment adjustment. In the alternative, we propose that a group practice participating in the GPRO would be required to elect to use the

administrative claims-based reporting mechanism in its self-nomination statement. We are proposing to provide less time for group practices to elect to use the administrative claims-based reporting mechanism because it is necessary for CMS to receive this information in the beginning of the applicable reporting period to indicate to CMS how these group practices should be analyzed throughout the reporting period. This early notification is especially important for large group practices, which may have hundreds or thousands of eligible professionals to track as a group practice. Therefore, we feel it is appropriate to request that a group practice elect to use the administrative claims-based reporting mechanism when the group practice self-nominates.

We further propose that an eligible professional or group practice would be required to make this election for each payment adjustment year the eligible professional or group practice seeks to be analyzed under this mechanism. For example, if the eligible professional seeks to report under the administrative claims mechanism for the 2015 and 2016 payment adjustments, the eligible professional would be required to make this election by the applicable deadline, for the 2015 payment adjustment and again by the applicable deadline, for the 2016 payment adjustment. We invite public comment on the proposed election requirement for eligible professionals and group practices electing to participate in the 2015 and 2016 payment adjustments using the administrative claims-based reporting mechanism.

b. Participation as a Group Practice in the GPRO

(1) Proposed Definition of Group Practice

We propose to modify §414.90(b) to define group practice as "a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN." We are proposing to change the number of eligible professionals comprising a PQRS group practice

from 25 or more to 2 or more to allow all groups of smaller sizes to participate in the GPRO. We believe that expanding the scope of group practices eligible to participate under the program will lead to greater program participation. To participate in the GPRO, a group practice would be required to meet this proposed definition at all times during the reporting period for the program year in which the group practice is selected to participate in the GPRO. We invite public comment on the proposed definition of group practice.

(2) Proposed Election Requirement for Group Practices Selected to Participate in the GPRO

We established the process for group practices to be selected to participate in the GPRO in the CY 2012 PFS final rule with comment period (76 FR 73316). However, this section contains additional processes with respect to a group practice's self-nomination statement that we are proposing for group practices selected to participate in the GPRO for 2013 and beyond. With respect to the requirement that group practices wishing to participate in the GPRO submit a self-nomination statement (76 FR 73316), for 2012, we accepted these self-nomination statements via a letter accompanied by an electronic file submitted in a format specified by CMS because it was not operationally feasible to receive self-nomination statements via the web at that time. In the CY 2012 Medicare PFS final rule with comment period, we noted that we anticipated that CMS would have the ability to collect self-nomination statements via the web for the 2013 Physician Quality Reporting System. We are therefore proposing that, for 2013 and beyond, a group practice must submit its self-nomination statement via the web.

We note that this web-based functionality is still being developed by CMS. Therefore, in the event this web-based functionality would not be available in time to accept self-nomination statements for the 2013 Physician Quality Reporting System, we propose that, in lieu of submitting self-nomination statements via the web, a group practice would be required to submit its self-nomination statement via a letter accompanied by an electronic file submitted in a format

specified by CMS (such as a Microsoft excel file). We propose that this self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-1850. If mailing the self-nomination statement, we would require that this self-nomination statement be received by no later than 5 PM Eastern Standard Time on January 31 of the year in which the group practice wishes to participate in the GPRO.

In the CY 2012 Medicare PFS final rule with comment period, we also established what information is required to be included in a group practice's self-nomination statement (76 FR 73316). In previous years, the group practice only had one reporting mechanism available on which to report data on PQRS quality measures: the GPRO web-interface. However, beginning 2013, we are proposing to allow group practices to report data on quality measures using the claims, registry, and EHR-based reporting mechanisms for the PQRS incentive and payment adjustment. Additionally, we are proposing to allow group practices to use the proposed administrative claims reporting option. We propose that a group practice wishing to participate in the GPRO for a program year would be required to indicate the reporting mechanism the group practice intends to use for the applicable reporting period in its self-nomination statement. Furthermore, once a group practice is selected to participate in the GPRO and indicates which reporting mechanism the group practice would use, we propose that the group practice would not be allowed to change its selection. Therefore, under this proposal, the reporting mechanism the group practice indicates it will use in its self-nomination statement for the applicable reporting period would be the only reporting mechanism under which CMS will analyze the group practice to determine whether the group practice has met the criteria for satisfactory reporting for the PQRS incentive and/or payment adjustment. We acknowledge that this proposal would depart

from the way we analyze an individual eligible professional, as CMS analyzes an individual eligible professional (who is permitted to use multiple reporting mechanisms during a reporting period) under every reporting method the eligible professional uses. Unfortunately, due to the complexity of analyzing group practices under the GPRO, such as having to associate multiple NPIs under a single TIN, it is not technically feasible for us to allow group practices using the GPRO to use multiple reporting mechanisms or switch reporting mechanisms during the reporting period. We invite public comment on the proposed election requirement and the proposed restriction noted above for group practices under the GPRO for 2013 and beyond.

(3) Proposed GPRO Selection Process

Group practices must be selected by CMS to participate in the PQRS GPRO for a program year. Please note that if a group practice is selected to participate in the PQRS as a GPRO, the eligible professionals in the selected group practice cannot participate in the PQRS individually. When selecting group practices to participate in the GPRO, CMS bases its decision on the information the group practice provides in its self-nomination statement. We believe that changes in a group practice's size or TIN constitute such a significant change in the group practice's composition that it would cause CMS to reconsider its decision to allow the group practice to participate in the GPRO for the applicable program year. Specifically, we understand that a group practice's size may vary throughout the program year. For example, we understand that eligible professionals enter into and leave group practices throughout the year. Similarly, we understand that group practices may undergo business reorganizations during the program year. We note that size fluctuations may affect the criteria under which a group practice would use to report after being selected to participate in the GPRO. As indicated in section III.G.4., we are proposing that groups of varying sizes be subject to different criteria for satisfactory reporting for the 2013 and 2014 incentives, as well as for the payment adjustments. Therefore, we propose

that, for analysis purposes, the size of the group practice must be established at the time the group practice is selected to participate in the GPRO. We invite public comment on this proposal.

We also understand that, for various reasons, a group practice may change TINs within a program year. For example, a group practice may undergo a mid-year reorganization that leads to the group practice changing its TIN mid-year. We propose that, if a group practice changes its TIN after the group practice is selected to participate in the GPRO, the group practice cannot continue participate in PQRS as a GPRO. We consider the changing of a group practice's TIN a significant change to the makeup of the group practice, as the group practice is evaluated under the TIN the group practice provided to CMS at the time the group is selected to participate in the GPRO for the applicable year. Therefore, we view a group practice that changes its TIN as an entirely new practice, associated with a new TIN. We understand that this proposal may pose a disadvantage for those group practices who find it beneficial to report PQRS quality measures using the GPRO. However, we note that eligible professionals in a group practice that has changed its TIN within a year may still participate as individuals. We invite public comment on this proposal.

We understand that a group practice may decide not to participate in PQRS using the GPRO after being selected. Therefore, we propose that group practices be provided with an opportunity to opt out of participation in the GPRO after selection. We note that it is necessary for a group practice to indicate to CMS the group practices' intent not to use the GPRO because, once a group practice is selected to participate in the GPRO for the applicable reporting period, CMS will not separately assess the NPIs associated with the group practice's TIN to see if they meet the criteria for satisfactory reporting for individual eligible professionals. Therefore, CMS must be notified of the group practice's decision not to participate in the GPRO so the eligible

professionals within the group practice could be assessed at the individual TIN/NPI level. We propose that group practices have until April 1 of the year of the applicable reporting period (for example, by April 1, 2013 for reporting periods occurring in 2013) to opt out of participating in the GPRO. We invite public comment on the proposed selection process for group practices wishing to participate in the GPRO.

(4) Proposed Requirement for Group Practices Electing to Use the Administrative Claims-based Reporting Mechanism for 2015 and 2016 Payment Adjustments

We propose an election requirement for group practices that elect to participate in the PQRS for the 2015 and 2016 payment adjustment using administrative claims-based reporting mechanism, which is discussed in full in section III.G.5. (which also addresses election requirements for eligible professionals). We seek comment on our proposal on election requirements for group practices that intend to report using the proposed administrative claims reporting option for the 2015 and 2016 payment adjustment.

2. Proposed Reporting Periods for the PQRS Payment Adjustments for 2016 and Beyond

For the PQRS incentives, we previously established 12 and 6-month reporting periods for satisfactorily reporting PQRS quality measures at §414.90(f)(1). Under section 1848(a)(8)(C)(iii) of the Act, we are authorized to specify the quality reporting period (reporting period) with respect to a payment adjustment year. We propose to modify the regulation to establish the reporting periods for the PQRS payment adjustments for 2015 and beyond.

For the 2015 payment adjustment, in the CY 2012 Medicare PFS final rule, we established CY 2013 (that is, January 1, 2013 through December 31, 2013) as the reporting period for the 2015 payment adjustment (76 FR 73392). We established a 12-month reporting period occurring 2 years prior to the application of the payment adjustments for group practices and for individual eligible professionals to allow time to perform all reporting analysis prior to

applying payment adjustments on eligible professionals' Medicare Part B PFS claims. However, we note that we might specify additional reporting periods for the 2015 payment adjustment. To coincide with the 6-month reporting period associated with the 2013 incentive for the reporting of measures groups via registry, we propose to modify the regulation at newly designated §414.90(h) to add a 6-month reporting period occurring July 1, 2013—December 31, 2013, for the 2015 payment adjustment for the reporting of measures groups via registry.

For 2016 payment adjustments, to coincide with the reporting periods for the 2014 incentive, we propose to modify the regulation at newly designated §414.90(h) to specify a 12-month (January 1, 2014 – December 31, 2014) and, for individual eligible professionals reporting measures groups via registry only, a 6-month (July 1, 2014—December 31, 2014) reporting periods for the 2016 payment adjustments.

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 a 6-month reporting period. Therefore, it is our intention to move towards using solely a 12-month reporting period once the reporting periods for the 2013 and 2014 incentives conclude. Therefore, for payment adjustments occurring in 2017 and beyond, we propose to modify the regulation at newly designated §414.90(h) to specify only a 12-month reporting period occurring January 1—December 31, that falls 2 years prior to the applicability of the respective payment adjustment (for example, January 1, 2015 through December 31, 2015, for the 2017 payment adjustment). We invite public comment on the proposed reporting periods for the PQRS payment adjustments for 2015 and beyond.

3. Proposed Requirements for the PQRS Reporting Mechanisms

3. Proposed Requirements for the PQRS Reporting Mechanisms

This section contains our proposals for the following reporting mechanisms: claims,

registry, EHR (including direct EHR products and EHR data submission vendor products), GPRO web-interface, and administrative claims. We previously established at §414.90(f)(2) that eligible professionals reporting individually may use the claims, registry, and EHR-based reporting mechanisms. We propose to modify §414.90 to allow group practices comprised of 2-99 eligible professionals to use the claims, registry, and EHR-based reporting mechanisms as well, because we recognize the need to provide varied reporting criteria for smaller group practices, particularly since we are proposing to expand the definition of group practice. For example, we understand that a smaller group practice may not have a sufficiently varied practice to be able to meet the proposed satisfactory reporting criteria for the GPRO web-interface that would require a smaller group practice to report on all of the proposed PQRS quality measures specified in Table 35. These proposals are reflected in our proposed changes to §414.90, which we are proposing to re-designate §414.90(g) and §414.90(h). We invite public comment on this proposal to make the claims, registry, and EHR-based reporting options applicable to group practices.

a. Claims-based Reporting: Proposed Requirements for Using Claims-based Reporting for 2013 and Beyond

Eligible professionals and group practices wishing to report data on PQRS quality measures via claims for the incentives and for the payment adjustments must submit quality data codes (QDCs) on claims to CMS for analysis. QDCs for the eligible professional's or group practice's selected PQRS (individual or measures groups) quality measures that are reported on claims may be submitted to CMS at any time during the reporting period for the respective program year. However, as required by section 1848(m)(1)(A) of the Act, all claims for services furnished during the reporting period, would need to be processed by no later than the last Friday occurring two months after the end of the reporting period, to be included in the program year's

PQRS analysis. For example, all claims for services furnished during a reporting period that occurs during calendar year 2013 would need to be processed by 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. In addition, after a claim has been submitted and processed, we propose at re-designated §414.90(g)(2)(i)(A) and newly added §414.90(h)(2)(i)(A) to indicate that EPs cannot submit QDCs on claims that were previously submitted and processed (for example, for the sole purpose of adding a QDC for the PQRS). We invite public comment on our proposed requirements for using the claims-based reporting mechanism for the incentives and for the payment adjustments for 2013 and beyond.

b. Registry-based Reporting

(1) Proposed Qualification Requirements for Registries for 2013 and Beyond

For 2013 and beyond, we propose that registries wishing to submit data on PQRS quality measures for a particular reporting period would be required to be qualified for each reporting period the registries wish to submit quality measures data. This qualification process is necessary to verify that registries are able to submit data on PQRS quality measures on behalf of eligible professionals and group practices to CMS. Registries who wish to become qualified to report PQRS quality measures for a reporting period undergo (1) a self-nomination process and (2) a qualification process regardless of whether the registry was qualified the previous program year.

For the self-nomination process, we propose that the self-nomination process would consist of the submission of a self-nomination statement submitted via the web by January 31 of each year in which the registry seeks to submit data on PQRS quality measures on behalf of eligible professionals and group practices. For example, registries that wish to become qualified to report data in 2013 under the program, that is, to report during all of the reporting periods for

the 2013 incentive and the 2015 payment adjustment, would be required to submit its self-nomination statement by January 31, 2013. We propose that the self-nomination statement contain all of the following information:

- The name of the registry.
- The reporting period start date the registry will cover.
- The measure numbers for the PQRS quality measures on which the registry is reporting.

We note that CMS is currently developing the functionality to accept registry self-nomination statements via the web and anticipate development of this functionality to be complete for registries to submit their self-nomination statements via the web in 2013. However, in the event that it is not technically feasible to collect this self-nomination statement via the web, we propose that registry vendors would 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, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-1850. We propose that these self-nomination statements must be received by CMS by 5:00 Eastern Standard Time on January 31 of the applicable year.

For the qualification process, we propose that all registries, regardless of whether or not they have been qualified to report PQRS quality measures in a prior program year, undergo a qualification process to verify that the registry is prepared to submit data on PQRS quality measures for the reporting period in which the registry seeks to be qualified. To become qualified for a particular reporting period, we propose that a registry would be required to:

- Be in existence as of January 1 the year prior to the program year in which the registry seeks qualification (for example, January 1, 2012, to be qualified to submit data in 2013).

- Have at least 25 participants by January 1 the year prior to the program year in which the registry seeks qualification (for example, January 1, 2012, to be qualified for the reporting periods occurring in 2013).

- Provide at least 1 feedback report to participating eligible professionals and group practices for each program year in which the registry submits data on PQRS quality measures on behalf of eligible professionals and group practices. This feedback reporting would be based on the data submitted by the registry to CMS for the applicable reporting period or periods occurring during the program year. For example, if a registry was qualified for the reporting periods occurring in 2013, the registry would be required to provide a feedback report to all participating eligible professionals and group practices based on all 12 and 6-month reporting periods for the 2013 incentive and the 12-month reporting period for 2015 payment adjustment. Although we propose to require that qualified registries provide at least 1 feedback report to all participating eligible professionals and group practices, we encourage registries to provide an additional, interim feedback report, if feasible, so that an eligible professional may determine what steps, if any, are needed to meet the criteria for satisfactory reporting.

- For purposes of distributing feedback reports to its participating eligible professionals and group practices, the registry must collect each participating eligible professional's e-mail address and have documentation from each participating eligible professional authorizing the release of his or her e-mail address.

- 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 PQRS registry).

- Participate in all ongoing PQRS mandatory support conference calls and meetings hosted by CMS for the program year in which the registry seeks to be qualified. For example, a

registry wishing to be qualified for reporting in 2013 would be required to participate in all mandatory support conference calls hosted by CMS related reporting in 2013 under the PQRS.

- Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures.
- Be able to calculate and submit measure-level reporting rates and/or, upon request, the data elements needed to calculate the reporting rates by TIN/NPI.
- Be able to calculate and submit, by TIN/NPI, a performance rate (that is, the percentage of a defined population who receive a particular process of care or achieve a particular outcome based on a calculation of the measure's numerator and denominator specifications) for each measure on which the eligible professional or group practice (as identified by the TIN/NPI) reports and/or, upon request, the Medicare beneficiary data elements needed to calculate the reporting rates.
- Be able to separate out and report on Medicare Part B FFS patients.
- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (reporting/performance numerator).
- Report the number of performance exclusions, meaning the quality action was not performed for a valid reason as defined by the measure specification.
- Report the number of reported instances, performance not met, meaning the quality action was not performed for any valid reason as defined by the measure specification. Please note that an eligible professional receives credit for reporting, not performance.
- Be able to transmit data on PQRS quality measures in a CMS-approved XML format.
- Comply with a CMS-specified secure method for data submission, such as submitting the registry's data in an XML file through an identity management system specified by CMS or

another CMS-approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.

- Submit an acceptable "validation strategy" to CMS by March 31 of the reporting year the registry seeks qualification (for example, if a registry wishes to become qualified for reporting in 2013, this validation strategy would be required to be submitted to CMS by March 31, 2013). A validation strategy details how the registry will determine whether eligible professionals and group practices have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method.

- Perform the validation outlined in the strategy and send the results to CMS by June 30 of the year following the reporting period (for example, June 30, 2014, for data collected in the reporting periods occurring in 2013).

- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the registry's receipt of patient-specific data from the eligible professionals and group practices, as well as the registry's disclosure of quality measure results and numerator and denominator data and/or patient-specific data on Medicare beneficiaries on behalf of eligible professionals and group practices who wish to participate in the PQRS.

- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on Medicare 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 registry to submit PQRS quality measures data to the 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 review the Medicare beneficiary data on which PQRS registry-based submissions are founded or provide to CMS a copy of the actual data.

- Provide CMS a signed, written attestation statement via mail or e-mail which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.

- Use PQRS measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. We will provide registries a standard set of logic to calculate each measure and/or measures group they intend to report for each reporting period.

- Provide a calculated result using the CMS-supplied measure calculation logic and XML file format for each measure that the registry intends to calculate. The registries may be required to show that they can calculate the proper measure results (that is, reporting and performance rates) using the CMS-supplied logic and send the calculated data back to CMS in the specified format. The registries will be required to send in test files with fictitious data in the designated file format.

- Describe to CMS the cost for eligible professionals and group practices that the registry charges to submit PQRS and/or eRx Incentive Program data to CMS.

- Agree to verify the information and qualifications for the registry prior to posting (includes names, contact, measures, cost, etc.) and furnish/support all of the services listed for

the registry on the CMS Website.

- Agree that the registry's data for Medicare beneficiaries may be inspected or a copy requested by CMS and provided to CMS under our oversight authority.
- Be able to report consistent with the satisfactory reporting criteria requirements for the PQRS incentives and payment adjustments.

In addition to meeting all the requirements specified previously for the reporting of individual quality measures via registry, for registries that intend to report on PQRS measures groups, we propose that these registries, regardless of whether or not registries were qualified in previous years, would be required to:

- Indicate the reporting period chosen for each eligible professional who chooses to submit data on measures groups.
- Base reported information on measures groups only on patients to whom services were furnished during the relevant reporting period.
- If the registry is reporting using the measures group option for 20 patients, the registry on behalf of the eligible professional may include non-identifiable data for non-Medicare beneficiaries as long as these patients meet the denominator of the measure and the eligible professional includes a majority Medicare Part B patients in their cohort of 20 patients for the measures group.

We intend to post the final list of registries qualified for each reporting period by the Summer of each the year in which the reporting periods occur on the CMS Website at http://http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html. For example, we intend to post the list of registries qualified for 2013 reporting periods by the Summer 2013. For each reporting period, the list of qualified registries would contain the following information: the registry name, registry contact

information, the measures and/or measures group(s) the registry is qualified and intends to report for the respective reporting period.

This proposed registry qualification process is largely the same process we established to qualify registries for the reporting periods occurring in 2012. We are proposing a similar process to the 2012 qualification process because, registries are already familiar with this qualification process, so we believe there would be a greater likelihood that registries wishing to be qualified to report quality measures data for a particular reporting period would be able to pass the qualification process. We believe this will provide eligible professional with more qualified registry products from which to choose.

Lastly, in the CY 2012 Medicare PFS proposed rule, we raised the issue of disqualifying registries that submit inaccurate data (76 FR 42845). We did not adopt a disqualification process but noted the importance of such a process, as well as our intention to provide detailed information regarding a disqualification process in future rulemaking (76 FR 73322). In an effort to ensure that registries provide accurate reporting of quality measures data, we propose to modify §414.90 to indicate that we would audit qualified registries. If, during the audit process, we find that a qualified registry has submitted grossly inaccurate data, we propose, under §414.90, to indicate that we would disqualify such a registry from the subsequent year under the program, meaning that a registry would not be allowed to submit PQRS quality measures data on behalf of eligible professionals and group practices for the next year. Under this proposal, a disqualified registry would not be included in the list of qualified registries that is posted for the applicable reporting periods under which the registry attempted to qualify. For example, if a qualified registry submits quality measures data for the reporting periods occurring in 2013 but is then audited and later disqualified, the registry would not be allowed to submit PQRS quality measures data on behalf of participating eligible professionals and group practices to CMS for

the reporting periods occurring in 2014 or later. One example of submitting grossly inaccurate data that CMS has encountered in the past is if a registry reports inaccurate TIN/NPIs on 5 percent or more of the registry's submission. As CMS calculates data on a TIN/NPI level, it is important for registries to provide correct TIN/NPI information. We invite public comment as to the threshold of grossly inaccurate data for the purpose of disqualifying a registry.

Under our proposal, our decision to disqualify would be final. We further propose to post a registry's disqualification status on the CMS Website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

In proposing registry disqualification, we considered other alternatives, such as placing registries in a probationary status. However, we believe it is important for registries to submit correct data once it is qualified to submit data on behalf of its eligible professionals and therefore, find that immediate disqualification to be appropriate. This becomes especially important particularly as the program moves from the use of incentives to payment adjustments.

We invite public comment on our proposals regarding registry qualification and disqualification for 2013 and beyond.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via a registry through NwHIN. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via registry for PQRS via NwHIN.

c. EHR-based Reporting

(1) Proposed Requirements for a Vendor's Direct EHR Products for 2014 and Beyond

We are proposing to modify §414.90(b) to define a direct electronic health record (EHR) product as "an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS." Please note that the self-nomination and qualification requirements for a vendor's direct EHR products for 2012 and 2013 were established in the CY 2012 Medicare PFS final rule (76 FR 73323).

In lieu of continuing this process in future years of the program, we propose to no longer require qualification of EHR products in order to be used for reporting under the PQRS. Although we would still allow EHR vendors to submit test files to the PQRS and continue to provide support calls, we would no longer require vendors to undergo this testing process. Although vendors and their products would no longer be required to undergo this testing or qualification process, we propose that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and
- In compliance with a CMS-specified secure method for data submission, such as submitting the direct EHR vendor's data (for testing) through an identity management system specified by CMS or another approved method.

In addition, upon request and for oversight purposes, we propose that the vendor would still be expected to provide CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data. CMS, however, would no longer be posting a list of qualified EHR vendors and their products on the CMS website. Therefore, eligible professionals would need to work with their respective EHR vendor to determine whether their specific EHR product has undergone any testing with the PQRS and/or whether their EHR product can produce and transmit the data in the CMS-specified format and manner. While we no longer believe that this process is necessary, we invite public

comment as to whether CMS should continue to require that direct EHR products undergo self-nomination and qualification processes prior to being authorized to submit quality measures data to CMS for PQRS reporting purposes.

We are proposing to not to continue the qualification requirement (that is, no longer propose this process for future years of the program) because we believe adequate checks are in place to ensure that a direct EHR product is able to submit quality measures data for the PQRS. For example, to the extent possible, we intend to align with the Medicare EHR Incentive Program with respect to our criteria for satisfactory reporting and measures available for reporting under the EHR-based reporting mechanism. The Medicare EHR Incentive Program requires that a vendor's EHR system be certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC). In future years, we anticipate that the ONC certification process could include testing related to the reporting of the proposed PQRS EHR measures indicated in Tables 32 and 33, since we are proposing to align the PQRS EHR-based measures with the measures available for reporting under the EHR Incentive Program. We invite public comment as to whether, in lieu of qualification, CMS should require that direct EHR products that would be used to submit data on PQRS quality measures for a respective reporting period be classified as certified under the program established by ONC.

Please note that, regardless of whether the qualification process is in place and not withstanding any CEHRT requirements that may apply, we note that eligible professionals bear the burden of determining choosing a direct EHR product that is able to adequately submit PQRS quality measures data to CMS.

We also invite public comment on the above proposals related to the proposed requirements for direct EHR products.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via a direct EHR product through NwHIN, but we would like to encourage this method with EHR-based reporting. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via an EHR for PQRS via NwHIN.

(2) Proposed Requirements for a Vendor's EHR Data Submission Vendor Products for 2013 and Beyond

The EHR data submission vendor reporting mechanism was a mechanism that was newly established in the CY 2012 Medicare PFS final rule (76 FR 73324). We indicated that these EHR data submission vendors, some of which included previous registries, were entities that are able to receive and transmit clinical quality data extracted from an EHR to CMS. We propose to modify §414.90(b) to define an electronic health record (EHR) data submission vendor as "an electronic health record vendor's product and version that acts as an intermediary to submit data on Physician Quality Reporting System measures on behalf of an eligible professional or group practice."

Please note that the qualification requirements for a vendor's EHR data submission vendor products for 2013 were established in the CY 2012 Medicare PFS final rule (76 FR 73327). Specifically, we established that a qualification and testing process would occur in 2012 to qualify EHR data submission vendor products to submit PQRS quality measures data for reporting periods occurring in CY 2013. Operationally, we were unable to establish a qualification and testing process in 2012 to qualify EHR data submission vendor products for reporting periods occurring in CY 2013. Therefore, we propose to perform, in 2013, the

qualification and testing process established in the CY 2012 Medicare PFS final rule (76 FR 73327) that was supposed to occur in 2012. We invite public comment on this proposal.

As for 2014 and beyond, we propose to no longer qualify EHR data submission vendor products in order to use such products under the PQRS for the same reasons we have articulated in our proposal not to continue qualifying direct EHR products. Although we would still allow EHR data submission vendors to submit test files to the PQRS and continue to provide support calls, we would no longer require vendors to undergo this testing process. Although EHR data submission vendor products would no longer be required to undergo this testing or qualification process, we propose that CMS would only accept the data if the data are:

- Transmitted in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 and for EHR data submission vendors who intend to report for purposes of the proposed PQRS Medicare EHR Incentive Program pilot, if the aggregate data are transmitted in a CMS-approved XML format
- In compliance with a CMS-specified secure method for data submission.

In addition, upon request and for oversight purposes, we propose that the vendor would still be expected to provide CMS access to review the Medicare beneficiary data on which PQRS direct EHR-based submissions are founded or provide to CMS a copy of the actual data. CMS, however, would no longer be posting a list of qualified EHR data submission vendors on the CMS website. Therefore, eligible professionals would need to work with their respective EHR data submission vendor to determine whether the vendor has undergone any testing with the PQRS and/or whether EHR data submission vendor can produce and transmit the data in the CMS-specified format and manner.

We invite public comment on our proposal to, beginning 2014, not require qualification

of EHR data submission vendor products. We also invite public comment as to whether CMS should continue to require that EHR data submission vendor products undergo these self-nomination and qualification processes prior to being authorized to submit quality measure data to CMS on an eligible professional's behalf for PQRS reporting purposes.

We are proposing to not to continue the qualification requirement (that is, no longer propose this process for 2014 and future years of the program) because we believe adequate checks are in place to ensure that a direct EHR product is able to submit quality measures data for the PQRS. For example, to the extent possible, we intend to align with the Medicare EHR Incentive Program with respect to our criteria for satisfactory reporting and measures available for reporting under the EHR-based reporting mechanism. The Medicare EHR Incentive Program requires that a vendor's EHR system be certified under the program established by the Office of the National Coordinator for Health Information Technology (ONC). In future years, we anticipate that the ONC certification process could include testing related to the reporting of the proposed PQRS EHR measures indicated in Tables 32 and 33, since we are proposing to align the PQRS EHR-based measures with the measures available for reporting under the EHR Incentive Program. We invite public comment as to whether, in lieu of qualification, CMS should require that EHR data submission vendor products wishing to submit data on PQRS quality measures for a respective reporting period be certified under the program established by ONC.

Please note that, if the qualification process is no longer required or we do not require that an EHR data submission vendor product be certified under ONC's program, we note that eligible professionals bear the burden of determining choosing an EHR data submission vendor product that is able to adequately submit PQRS quality measures data to CMS.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative

developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via an EHR data submission vendor through NwHIN, but we would like to encourage this method with EHR-based reporting. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via an EHR for PQRS via NwHIN.

d. GPRO Web-Interface: Proposed Requirements for Group Practices Using the GPRO Web-Interface for 2013 and Beyond

The GPRO web-interface is a reporting mechanism established by CMS that is used by group practices that are selected to participate in the GPRO. For 2013 and beyond, we propose to modify newly designated §414.90(g) and §414.90(h) to identify the GPRO web-interface as a reporting mechanism available for reporting under the PQRS by group practices comprised of 25 or more eligible professionals. Consistent with the GPRO satisfactory reporting criteria we established for the 2012 PQRS (76 FR 73338), as well as the GPRO satisfactory reporting criteria we are proposing for 2013 and beyond, we propose to limit reporting via the GPRO web-interface during a respective reporting period to group practices comprised of at least 25 eligible professionals (that is, this reporting option would not be available to group practices that contain 2-24 eligible professionals) and selected to participate in the GPRO for the year under which the reporting period occurs. For example, a group practice wishing to submit quality measure data via the GPRO web-interface for 2013 must be a group practice selected to participate in the GPRO for the 2013 program year. We believe it is necessary to limit use of the GPRO web-interface to group practices comprised of at least 25 eligible professionals selected to participate in the GPRO because the 17 measures that are proposed to be reportable via the GPRO web-interface (as specified in Table 35) reflect a variety of disease modules: patient/ caregiver

experience, care coordination/patient safety, preventive health, diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease.

We believe that the reporting of these 18 proposed measures spanning across various settings lends this reporting mechanism more ideal for larger group practices that are more likely to be multi-specialty practices (which are typically group practices consisting of larger than 25 eligible professionals). The GPRO web-interface was modeled after the CMS Physician Group Practice (PGP) demonstration, and this demonstration was originally intended for large group practices. From our experience with the PGP demonstration, we believe a group practice comprised of 25 eligible professionals is the smallest group practice that could benefit from use of the GPRO web-interface as a reporting mechanism. We also do not believe that excluding group practices comprised of 2-24 eligible professionals from using the GPRO web-interface as a reporting mechanism would harm these smaller group practices as we are proposing to allow groups comprised of 2-99 eligible professionals to report using the claims, qualified registry, EHR, and administrative claims-based reporting mechanisms.

We propose to 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. For example, for group practices selected for the GPRO for the 2013 incentive using the GPRO web-interface tool, we propose to provide group practices selected to participate in the GPRO 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. In addition, should CMS encounter operational issues with using the GPRO web-interface, we reserve the right to use a similar tool for group practices to use in lieu of reporting via the GPRO

web-interface. We invite public comment on our proposed requirements for group practices using the GPRO web-interface for 2013 and beyond.

In addition, the Nationwide Health Information Network (NwHIN) is an initiative developed by the Department of Health and Human Services that provides for the exchange of healthcare information. Traditionally, CMS has not collected data received via the GPRO web-interface through NwHIN. However, we strive to encourage the collection of data via the NwHIN and intend to do so when it is technically feasible to do so (as early as 2014). Therefore, we seek public comment on collecting data via the GPRO web-interface for PQRS via NwHIN.

e. Administrative Claims

For purposes of reporting for the 2015 and 2016 PQRS payment adjustments only, we propose to modify §414.90(h) to allow eligible professionals and group practices to use an administrative claims reporting mechanism. The administrative claims reporting mechanism builds off of the traditional PQRS claims-based reporting mechanism. Under the traditional PQRS claims-based reporting mechanism, eligible professionals and group practices wishing to report data on PQRS quality measures via claims for the incentives and for the payment adjustments must submit quality data codes (QDCs) on claims to CMS for analysis. Under the proposed administrative claims reporting mechanism, unlike the traditional claims-based reporting option, an eligible professional or group practice would not be required to submit QDCs on claims to CMS for analysis. Rather, CMS would analyze every eligible professional's or group practice's patient's Medicare claims to determine whether the eligible professional or group practice has performed any of the clinical quality actions indicated in the proposed PQRS quality measures in Table 63. We propose that, for purposes of assessing claims for quality measures under this option, all claims for services furnished that occurs during the 2015 and/or 2016 PQRS reporting period would need to be processed by no later than 60 days after the end of

the respective 2015 and 2016 payment adjustment reporting periods (that is, December 31, 2013 and December 31, 2014). We invite public comment on our proposed requirements for using the administrative claims-based reporting mechanism for the 2015 and 2016 payment adjustments.

4. Proposed Criteria for Satisfactory Reporting for the 2013 and 2014 Incentives

For 2013 and 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. This section contains our proposed criteria for satisfactory reporting for the 2013 and 2014 incentives, which are the last two incentives authorized under the PQRS.

a. Proposed Criteria for Satisfactory Reporting for Individual Eligible Professionals

Please note that, in large part, we are proposing many of the same criteria for satisfactory reporting for individual eligible professionals for the 2013 and 2014 incentives that we established for the 2012 incentive, as eligible professionals are already familiar with these reporting criteria.

(1) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via Claims

According to the "2010 Physician Quality Reporting System and eRx Reporting Experience and Trends," available for viewing in the "downloads" section of the main page the PQRS website (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html), reporting via the claims-based reporting mechanism was the most commonly used reporting method. We believe that this trend continues, so we anticipate that, with respect to the 2013 and 2014 incentives, the criteria for satisfactory reporting for the claims-based reporting mechanism will be the method most widely used by individual eligible

professionals. So as not to change reporting criteria that a large number of individual eligible professionals are familiar with using, we established the same reporting criteria for the 2011 and 2012 incentives (76 FR 73330). Therefore, for the respective 12-month reporting periods for the 2013 and 2014 incentives, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting specified under the statute and our desire to maintain the same reporting criteria we established for individual eligible professionals for the 2012 PQRS incentive (76 FR 73330), we propose the following criteria for satisfactory reporting of PQRS individual measures for individual eligible professionals using the claims-based reporting mechanism: 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, we propose that the eligible professional 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. We believe the MAV process is necessary to review whether there are other closely related measures (such as those that share a common diagnosis or those that are representative of services typically provided by a particular type of eligible professional). Under the MAV process, if an eligible professional who reports on fewer than 3 measures reports on a measure that is part of an identified cluster of closely related measures, then the eligible professional would not qualify as a satisfactory reporter for the 2013 and/or 2014 incentives. We are proposing this MAV process for the claims-based reporting mechanism only because it is more likely for EPs to report on more than 3 measures under the registry and EHR-based reporting mechanisms, as a registry or EHR product will

typically automatically report on all measures that apply to the eligible professional's practice. We note that, consistent with section 1848(m)(3)(A)(i) of the Act, this proposed claims-based reporting criteria is the only proposed criteria where an eligible professional may report on fewer than 3 measures. We invite public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via claims for the 2013 and 2014 incentives.

(2) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via Registry

In addition, we note that section 1848(m)(3)(A)(ii) of the Act provides that, to meet the criteria for satisfactory reporting under PQRS, an eligible professional would be required to report on at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Although we have the authority under section 1848(m)(3)(D) of the Act to revise the criteria for satisfactory reporting, with respect to registry-based reporting, we have largely followed these reporting criteria for the PQRS incentives. According to the "2010 Physician Quality Reporting System and eRx Reporting Experience and Trends," eligible professionals are more likely to meet the requirements for a PQRS incentive using the satisfactory reporting criteria for the registry-based reporting mechanism than claims. In fact, in 2010, approximately 87 percent of the eligible professionals reporting individual PQRS quality measures via registry were eligible and met the criteria for satisfactory reporting for the 2010 incentive. Since eligible professionals have had success with using these satisfactory reporting criteria, we believe such criteria are appropriate and see no reason to change the criteria for satisfactory reporting via registry that has been in place since 2010. Therefore, for those reasons and our desire to maintain the same reporting criteria we established for individual eligible professionals for the 2012 PQRS incentive (76 FR 73331), we propose the following criteria for

satisfactory reporting of PQRS individual measures for individual eligible professionals using the registry-based reporting mechanism for the 12-month reporting periods for the 2013 and 2014 incentives, respectively: 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 zero percent performance rate will not be counted. Measures with a zero percent performance rate will not be counted. We invite public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via a registry for the 2013 and 2014 incentives.

(3) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures via EHR

As stated previously, section 1848(m)(7) of the Act requires us to develop a plan to integrate reporting requirements for PQRS and the EHR Incentive Program. Therefore, with respect to EHR-based reporting, it is our main goal to align our EHR reporting requirements with the reporting requirements an eligible professional must meet in order to satisfy the clinical quality measure (CQM) component of meaningful use (MU) under the EHR Incentive Program. In the EHR Incentive Program – Stage 2 NPRM (77 FR 13698), we proposed the CQM reporting requirements for the EHR Incentive Program for 2013, 2014, 2015, and potentially subsequent years. For the EHR reporting periods in CY 2013, we proposed (77 FR 13745) to continue the CQM reporting requirements that were established for eligible professionals for CYs 2011 and 2012 in the EHR Incentive Program – Stage 1 final rule (75 FR 44398-44411). Therefore, to align with the reporting requirements for meeting the CQM component of meaningful use, and based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting identified under the statute, we propose the following criteria for the 12-month reporting period for the 2013 incentive:

● As required by the Stage 1 final rule, eligible professionals must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44398 through 44411).

Under this proposal, eligible professionals using these reporting criteria would be required to report on 6 measures. For the proposed PQRS EHR measures that are also Medicare EHR Incentive Program core, alternate core, or additional measures that the eligible professional reports (75 FR 44398 through 44411), an eligible professional would be required to report the applicable measure for 100 percent of the eligible professionals Medicare Part B FFS patients.

In addition, we note that section 1848(m)(3)(A)(ii) of the Act provides that, to meet the criteria for satisfactory reporting under PQRS, an eligible professional would be required to report on at least 3 measures for at least 80 percent of the cases in which the respective measure is reportable under the system. Although we have the authority under section 1848(m)(3)(D) of the Act to revise the criteria for satisfactory reporting, for EHR-based reporting, we have largely kept these reporting criteria for the 2010—2012 incentives. As we have seen some eligible professionals succeed with these criteria, we are proposing the following similar criteria for the 12-month reporting period for the 2013 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 zero percent performance rate will not be counted.

We note that the Medicare EHR Incentive Program has proposed options for meeting the CQM component of achieving meaningful use beginning with CY 2014 (for more information

on these options, please see 77 FR 13746—13748). To align our EHR-based reporting requirements with those proposed under the Medicare EHR Incentive Program, we are proposing the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive:

- Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.

- Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33. It is our intention to finalize the reporting criteria that aligns with the criteria that will be established for meeting the CQM component of meaningful use beginning with CY 2014 for the Medicare EHR Incentive Program. Furthermore, to the extent that the final criteria for meeting the CQM component of achieving meaningful use differ from what was proposed, our intention is to align with the reporting criteria the EHR Incentive Program ultimately establishes. Therefore, eligible professionals who participate in both PQRS and the EHR Incentive Program would be able to use one reporting criterion, during overlapping reporting periods, to satisfy the satisfactory reporting criteria under PQRS and the CQM component of meaningful use under the Medicare EHR Incentive Program. We invite public comment on this considered proposal.

In addition to this proposed criterion, the Medicare EHR Incentive Program proposed that, beginning with CY 2014, eligible professionals who participate in both the Physician Quality Reporting System and the Medicare EHR Incentive Program may satisfy the CQM

component of meaningful use if they submit and satisfactorily report Physician Quality Reporting System clinical quality measures under the Physician Quality Reporting System's EHR reporting option using Certified EHR Technology (77 FR 13748). Since this language suggests that the Medicare EHR Incentive Program may defer to the satisfactory reporting criteria for the EHR-based reporting mechanism that we will establish for 2014, we are proposing the following reporting criteria for the 12-month reporting period for the 2014 incentive that largely conform to the criteria set forth under section 1848(m)(3)(A)(ii) of the Act that we established for the 2012 incentive and that we are proposing for the 2013 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 zero percent performance rate will not be counted. We invite public comment on the proposed criteria for satisfactory reporting on PQRS measures via EHR.

(4) Proposed Criteria for Satisfactory Reporting on PQRS Measures Groups via Claims

In the CY 2012 Medicare PFS final rule, we established the following criteria for satisfactorily reporting PQRS measures groups for the 12-month reporting period for the 2012 incentive (76 FR 73335):

- Report at least 1 PQRS measures group, AND report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted; OR

- Report at least 1 PQRS measures group, AND report each measures group for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be

counted.

We received stakeholder feedback that it is difficult for some specialties to meet the 30 Medicare Part B FF patient threshold. Therefore, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, we propose the following criteria for the satisfactory reporting PQRS measures groups for individual eligible professionals using the claims-based reporting mechanism for the 12-month reporting periods for the 2013 and 2014 incentives: 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.

We note that, in an effort to simplify the satisfactory reporting criteria, we are only proposing 1 option for meeting the criteria for satisfactory reporting using PQRS measures groups via claims. We invite public comment on the proposed criterion for satisfactory reporting of measures groups via claims for the 2013 and 2014 incentives.

(5) Proposed Criteria for Satisfactory Reporting on PQRS Measures Groups via Registry

In the CY 2012 Medicare PFS final rule, we established the following criteria for satisfactorily reporting PQRS measures groups for the 12-month reporting period for the 2012 incentive (76 FR 73337):

- Report at least 1 PQRS measures group AND report each measures group for at least 30 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted; OR

- Report at least 1 PQRS measures group, AND report each measures group for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 15 Medicare Part B FFS patients seen during the reporting period to which the measures group

applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

In addition, we established the following criteria for satisfactorily reporting PQRS measures groups for the 6-month reporting period for the 2012 incentive (76 FR 73337): Report at least 1 PQRS measures group, AND report each measures group for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT report each measures group on no less than 8 Medicare Part B FFS patients seen during the reporting period to which the measures group applies. Measures groups containing a measure with a 0 percent performance rate will not be counted.

We received stakeholder feedback that it is difficult for some specialties to meet the 30 Medicare Part B FF patient threshold. Therefore, based on our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, we propose the following criteria for satisfactory reporting of PQRS measures groups for individual eligible professionals using the registry-based reporting mechanism for the 2013 and 2014 incentives:

(1) For the 12-month reporting periods for the respective 2013 and 2014 incentives, report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(2) For the 6-month reporting period for the respective 2013 and 2014 incentives, report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures group containing a measure with a zero percent performance rate will not be counted. Please note that this is the same criterion established for the 12-month reporting period. We are proposing the same criterion for both reporting periods in an effort to simplify the reporting criterion for satisfactory reporting.

We note that, while we still are proposing to require that an eligible professional report on at least 20 patients, we understand that a patient's personal identification information may be stripped when data is collected via a qualified registry. As such, we understand that it may be difficult to distinguish Medicare and non-Medicare patients. Given this difficulty and that the eligible professionals generally would be attempting to report data on Medicare patients, we believe the reporting of some non-Medicare patients could serve a proxy for the reporting of Medicare patients whose data is not easily distinguishable as data on Medicare patients under this reporting mechanism.

Finally, we note that these proposals would satisfy the requirement under section 1848(m)(5)(F) of the Act that we provide for alternative reporting periods and criteria for satisfactory reporting with regard to measures groups and registry-based reporting. We invite public comment on the proposed criteria for satisfactory reporting of measures groups by individual eligible professionals via registry for the 2013 and 2014 incentives.

Tables 25 and 26 provide a summary of our proposals for the satisfactory reporting of PQRS quality measures for the 2013 and 2014 incentives.

**Table 25: Proposed Criteria for Satisfactory Reporting by Individual Eligible Professionals of Data on PQRS Quality Measures for the 2013 Incentive**

| Reporting Period | Measure Type | Reporting Mechanism | Proposed Reporting Criteria |
|---|---|---|---|
| Jan 1, 2013—Dec 31, 2013* | Individual Measures | Claims | Report at least 3 measures, OR,<br>If less than 3 measures apply to the eligible professional, report 1—2 measures*; AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| Jan 1, 2013—Dec 31, 2013 | Individual Measures | Qualified Registry | Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| Jan 1, 2013—Dec 31, 2013 | Individual Measures | Direct EHR Product | Option 1: Report on ALL three PQRS EHR measures that are also Medicare EHR Incentive Program core measures.<br>If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three PQRS EHR measures that are also Medicare EHR Incentive Program alternate core measures; |

| Reporting Period | Measure Type | Reporting Mechanism | Proposed Reporting Criteria |
|---|---|---|---|
| | | | AND<br>Report on three additional PQRS EHR measures that are also measures available for the Medicare EHR Incentive Program<br><br>Option 2: Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| Jan 1, 2013—Dec 31, 2013 | Individual Measures | EHR Data Submission Vendor | Option 1: Report on ALL three PQRS EHR measures that are also Medicare EHR Incentive Program core measures.<br>If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three PQRS EHR measures that are also Medicare EHR Incentive Program alternate core measures; AND<br>Report on three additional PQRS EHR measures that are also measures available for the Medicare EHR Incentive Program<br><br>Option 2: Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| Jan 1, 2013—Dec 31, 2013 | Measures Groups | Claims | Report at least 1 measures group, AND<br>Report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted. |
| Jan 1, 2013—Dec 31, 2013 | Measures Groups | Qualified Registry | Report at least 1 measures group, AND<br>Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.<br>Measures groups containing a measure with a 0 percent performance rate will not be counted |
| Jul 1, 2013—Dec 31, 2013 | Measures Groups | Qualified Registry | Report at least 1 measures group, AND<br>Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.<br>Measures groups containing a measure with a 0 percent performance rate will not be counted |

* Subject to the measure applicability validation (MAV) process.

**Table 26: Proposed Criteria for Satisfactory Reporting by Individual Eligible Professionals of Data on PQRS quality measures for the 2014 Incentive**

| Reporting Period | Measure Type | Reporting Mechanism | Proposed Reporting Criteria |
|---|---|---|---|
| Jan 1, 2014—Dec 31, 2014* | Individual Measures | Claims | Report at least 3 measures, OR,<br>If less than 3 measures apply to the eligible professional, report 1—2 measures*; AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| Jan 1, 2014—Dec 31, 2014 | Individual Measures | Qualified Registry | Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |

| Reporting Period | Measure Type | Reporting Mechanism | Proposed Reporting Criteria |
|---|---|---|---|
| Jan 1, 2014—Dec 31, 2014 | Individual Measures | Direct EHR product | Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.<br><br>Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33plus 1 menu clinical quality measure from Tables 32 and 33.<br><br>Option 2: 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 zero percent performance rate will not be counted. |
| Jan 1, 2014—Dec 31, 2014 | Individual Measures | EHR data submission vendor | Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.<br><br>Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33plus 1 menu clinical quality measure from Tables 32 and 33.<br><br>Option 2: 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 zero percent performance rate will not be counted. |
| Jan 1, 2014—Dec 31, 2014 | Measures Groups | Claims | Report at least 1 measures group, AND<br>Report each measures group for at least 20 Medicare Part B FFS patients.<br>Measures groups containing a measure with a 0 percent performance rate will not be counted. |
| Jan 1, 2014—Dec 31, 2014 | Measures Groups | Qualified Registry | Report at least 1 measures group, AND<br>Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.<br>Measures groups containing a measure with a 0 percent performance rate will not be counted. |
| Jul 1, 2014—Dec 31, 2014 | Measures Groups | Qualified Registry | Report at least 1 measures group, AND<br>Report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients.<br>Measures groups containing a measure with a 0 percent performance rate will not be counted. |

* Subject to the measure applicability validation (MAV) process.

b. Proposed Criteria for Satisfactory Reporting for Group Practices Selected to Participate in the GPRO

This section contains our proposed criteria for satisfactory reporting for group practices

selected to participate in the GPRO for the 2013 and 2014 incentives, which are the last two incentives authorized under the Physician Quality Reporting System. Please note that, in addition to offering the GPRO web-interface tool that we've previously included under the program, we are proposing new criteria for group practices under the GPRO that allow group practices to use the claims, registry, and EHR-based reporting mechanisms. In prior program years, large group practices have been successful in reporting quality measures data via the GPRO web-interface. We are proposing new criteria under the claims, qualified registry, and EHR-based reporting mechanisms because we believe that smaller groups may benefit from different reporting criteria and also other reporting mechanisms. Since the introduction of smaller group practices comprised of 25-99 eligible professionals under the GPRO is fairly recent, and given that we are proposing to modify the definition for group practice such that the PQRS GPRO would include beginning in 2013 group practices comprised of 2-24 eligible professionals, we are proposing additional criteria for reporting because we believe it may be more practicable that smaller group practices report on PQRS quality measures via claims, qualified registry, or direct EHR or EHR data submission vendor versus the GPRO web-interface, which was designed for use by larger group practices.

(1) Proposed Criteria for Beneficiary Assignment Methodology and Satisfactory Reporting on PQRS Quality Measures via the GPRO Web-Interface

In order to populate the GPRO web-interface, we must first assign beneficiaries to each group practice and then from those assigned beneficiaries draw a sample of beneficiaries for the disease modules in the GPRO web interface. This assignment and sampling methodology is based on what we learned from the PGP demonstration. The PGP demonstration aims to encourage coordination of the care furnished to individuals under Medicare parts A and B by institutional and other providers, practitioners, and suppliers of health care items and services;

encourage investment in administrative structures and processes to ensure efficient service delivery; and reward physicians for improving health outcomes and reducing the rate of growth in health care expenditures. In the PGP Transition demonstration, the goal of beneficiary assignment criteria is to identify Medicare beneficiaries that have a plurality of their allowed charges for office evaluation and management (E & M) services furnished at a participating PGP during the year. If they do not have any primary care physician visits, then they are assigned using plurality of allowed charges for all office E & M physician visits regardless of specialty.

In 2012, the beneficiaries that we assigned to group practices, for purposes of reporting on the PQRS quality measures via the GPRO web-interface, were limited to those Medicare Part B FFS beneficiaries with Medicare Parts A and B claims for whom Medicare is the primary payer. Assigned beneficiaries did not include Medicare Advantage enrollees. We assigned a beneficiary to the group practice if the practice provided the plurality of a beneficiary's office or other outpatient office evaluation and management allowed charges. Beneficiaries with only one office visit to the group practice were eliminated from the group practice's assigned patient population. Please note that, for the GPRO web-interface, similar to the PGP demonstration, also takes eligible professional services other than physician services when evaluating a group practice's office E & M services. We are proposing to continue using this assignment methodology for 2013 and subsequent years because it is already in place operationally. We believe the assignment methodology we are currently using adequately captures sufficient data to reflect the quality of care furnished by group practices reporting under the GPRO web-interface. We invite public comment on our proposal to continue to use this methodology for assigning beneficiaries.

We note that the Medicare Shared Savings Program uses a somewhat different assignment methodology. More information regarding the assignment methodology that is used

in the Shared Savings Program be found on the program website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/. However, we note that consistent with the requirements of section 1899(c) of the Act, the assignment methodology used in the Shared Savings Program (which involves a 2-step process) has a greater focus on physician-provided primary care services.

In order to more closely align with the Medicare Shared Savings Program, we considered proposing to modify the assignment method PQRS uses to assign beneficiaries to a group practice to be similar to the two-step assignment method specified in §425.402 that is used under the Medicare Shared Savings Program to assign beneficiaries to an ACO. Consistent with that two-step methodology, in order for a beneficiary to be eligible for assignment to a group practice, the beneficiary must have received at least one primary care service from a physician (as defined in §425.20) within the group practice during the reporting period. Accordingly, we would identify beneficiaries who received at least one primary care service from any group practice physician (regardless of specialty) participating in the group practice during the reporting period. Under the first assignment step, we would assign the beneficiary to the group practice if the beneficiary had at least one primary care service furnished by a primary care physician at the participating group practice, and more primary care services (measured by Medicare allowed charges) furnished by primary care physicians in the participating group practice than furnished by primary care physicians at any other group practice or non-group practice physician. The second step applies only for those beneficiaries who do not receive any primary care services from a primary care physician during the reporting period. We would assign the beneficiary to the participating group practice in this step if the beneficiary had at least one primary care service furnished by a group practice physician, regardless of specialty, and

more primary care services were furnished by group practice professionals (including non-primary care physicians, nurse practitioners, physician assistants or clinical nurse specialists) (measured by Medicare allowed charges) at the participating group practice than at any other group practice or non-group practice physician. We would then pull samples of beneficiaries for the relevant measures/modules from this population of assigned beneficiaries to populate the GPRO web interface. We considered making this change to the assignment method beginning with the 2013 PQRS GPRO web-interface so that the rules used to assign beneficiaries to group practices participating in PQRS and ACOs participating in the Medicare Shared Savings Program would be consistent. Since both group practices that are participating in the PQRS GPRO and ACOs participating in the Medicare Shared Savings Program would be using the same GPRO web interface to report the same set of quality measures to CMS, we believe that applying consistent assignment methods across the two programs would allow us to streamline our processes and could potentially reduce confusion among group practices considering participation in the PQRS GPRO or ACOs considering participation in the Medicare Shared Savings Program. We invite public comment on this alternative option of adopting a methodology similar to the one the Medicare Shared Savings Program uses to assign beneficiaries to ACOs to assign beneficiaries to group practices that report on PQRS quality measures via the GPRO web-interface beginning in 2013.

Consistent with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we propose the following criteria for the satisfactory reporting of PQRS quality measures for group practices selected to participate in the GPRO for the 12-month reporting periods for the 2013 and 2014 incentives, respectively, using the GPRO Web-interface for groups practices 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 disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology CMS provides will not be able to assign at least 218 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25-99 eligible professionals. If the group practice is assigned less than 218 Medicare beneficiaries, then the group practice would report on 100 percent of its assigned beneficiaries. In addition, we propose the following criteria for the satisfactory reporting of PQRS quality measures for group practices selected to participate in the GPRO for the 2013 and 2014 incentives, respectively, using groups practices of 100 or more eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries.

The satisfactory criteria we proposed for the GPRO web-interface for large group practices for the 2013 and 2014 incentives is consistent with the reporting criteria we established for the 2012 PQRS incentive (76 FR 73339). The satisfactory criteria we proposed for groups of 25-99 eligible professionals are consistent with the reporting criteria we established for the 2012 PQRS incentive (76 FR 73339). We are proposing these same criteria because the thresholds proposed in these criteria are based on analysis performed on group reporting based on the PGP demonstration to determine reasonable thresholds for group practice reporting. Therefore, we believe the satisfactory reporting criteria that we have proposed for the GPRO web-interface for the 2013 and 2014 incentives are appropriate criteria and reasonable for groups to meet.

Furthermore, we propose using Medicare Part B claims data for dates of service on or

after January 1 and submitted and processed by approximately the last Friday in October of the applicable 12-month reporting period under which the group practice participates in the GPRO to assign Medicare beneficiaries to each group practice. For example, for a group practice participating under the GPRO for the reporting periods occurring in 2013, for the sampling model, we propose that we would assign beneficiaries on which to report based on Medicare Part B claims with dates of service beginning January 1, 2013 and processed by October 25, 2013. We invite public comment on our proposal to continue to use this methodology for assigning beneficiaries.

(2) Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Selected to Participate in the GPRO via Claims, Registry, and EHR

We are proposing to have the claims, registry, and EHR reporting mechanisms available for group practices of 2-99 eligible professionals to use to report PQRS quality measures. We note that we are not proposing to make the claims, registry, and EHR reporting mechanisms available to larger groups of 100 or more eligible professionals, because we believe that these larger group practices do not face the potential limitations that smaller group practices may face when using the GPRO web-interface. Although group practices of 100-249 were also only introduced to the GPRO web-interface in 2012, we note that we believe these practices are sufficiently large enough to account for the varied measures required for reporting under the GPRO web-interface. For example, the proposed criteria for satisfactory reporting on individual PQRS quality measures for group practices using the GPRO web-interface would require a group practice to report on all 18 measures that are indicated in Table 35. Larger group practices tend to have more varied practices, so it would be easier for larger groups to report on a measure set that covers multiple domains, such as the one proposed in Table 35, than smaller group practices that tend to be focused on a limited set of specialties. We certainly think this is the case for the

smallest group practices comprised of 2-24 eligible professionals, which is the reason why we are not proposing that the GPRO web-interface be available for use for these smaller group practices. With respect to group practices comprised of 25-99 eligible professionals, we believe it is possible for these group practices to have a practice that is sufficiently varied to be able to report on measures that cut across multiple domains. However, we note that use of the GPRO web-interface as a reporting mechanism was only introduced to groups of 2-99 in 2012, so no data is available to determine the feasibility of groups of 25-99 using the GPRO web-interface. Therefore, in the event these groups feel that reporting using the GPRO web-interface would be difficult, we are proposing criteria alternative to that proposed under the GPRO web-interface for satisfactory reporting for the 2013 and 2014 incentives using the claims, registry, and EHR-based reporting mechanisms that mirror the criteria we are proposing for individual reporting for the claims, registry, and EHR-based reporting mechanisms from the 2013 and 2014 incentives. We note that the criteria we are proposing for the 2013 and 2014 incentives using the claims, registry, and EHR-based reporting mechanisms are similar to the criteria for individual reporting, because we believe smaller group practices are more akin to individuals with respect to practice scope. The larger the group practice, the more likely the group practice would benefit using the reporting options under the GPRO web-interface.

Therefore, based on our authority under section 1848(m)(3)(C) of the Act, we propose the following satisfactory reporting criteria via claims for group practices comprised of 2-99 eligible professionals under the GPRO for the 2013 and 2014 incentives via claims: Report at least 3 measures AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

For those group practices that choose to report using a qualified registry, we propose the

following satisfactory reporting criteria via qualified registry for group practices comprised of 2-99 eligible professionals under the GPRO for the 2013 and 2014 incentives: 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 zero percent performance rate will not be counted. Please note that we are only proposing these satisfactory reporting criteria for group practices comprised of 2-99 eligible professionals because we believe that larger group practices should have the technical capacity and resources to report on the more expansive measure set that is collected via the GPRO web-interface.

For group practices choosing to report PQRS quality measures via EHR, we propose the following 2 options for the satisfactory reporting criteria via a direct EHR product or EHR data submission vendor for group practices comprised of 2-99 eligible professionals under the GPRO for the 2013 incentive:

Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals reporting those CQMs (75 FR 44398 through 44411).

Option 2: 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 zero percent performance rate will not be counted.

We note that the Medicare EHR Incentive Program has proposed 2 options for meeting the CQM component of achieving meaningful use beginning with CY 2014 (for more information on these options, please see 77 FR 13746—13748). To align our EHR-based

reporting requirements with those proposed under the Medicare EHR Incentive Program, we are proposing the following criteria for satisfactory reporting using the EHR-based reporting mechanism for the 12-month reporting period for the 2014 incentive:

- Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.

- Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33. We propose to adopt the group reporting criteria that aligns with the criteria that will be established for meeting the CQM component under CY 2014 for the Medicare EHR Incentive Program. Furthermore, to the extent that the final group reporting criteria for meeting the CQM component of achieving meaningful use differ from what was proposed, our intention is to align with the group reporting criteria the EHR Incentive Program ultimately establishes. We invite public comment on this proposal.

We also considered proposing the following satisfactory reporting criteria for the 2014 PQRS incentive for groups of 2-99 that was similar to the satisfactory reporting criteria being proposed for the 2013 PQRS incentive: 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 zero percent performance rate will not be counted. We invite public comment on this considered proposal.

We note that we believe these proposed criteria meets the requirements for group practice reporting specified in section 1848(m)(3)(C) of the Act. Section 1848(m)(3)(C) requires that the

criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration. We note that, although these criteria depart from the model used in the PGP demonstration, we believe that these criteria still meet the statistical sampling model requirement in that the group practices would still be required to report the measures on a sample of their patients. Rather than CMS choosing which sample of patients the group practice must report, with these proposed criteria, the group practice decides on which sample of patients to report for either 50 percent, 80 percent, or 100 percent of its patients depending on the reporting mechanism the group practice chooses. For example, if a group practice who sees 100 patients during the 2013 incentive reporting period chooses to report PQRS quality measures using the claims-based reporting mechanism, for the 2013 incentive, the group practice would have to report at least 3 measures for 50 percent of the practice's patients. The group practice may pick which patients on which to report, as long as the group practice reports on at least 50 of the patients the practice sees in 2013. If the same group practice decides to report on PQRS quality measures using the Option 1 criteria for EHR-based reporting for the 2013 incentive, the group practice would report on all 100 patients. We note that although reporting on 100 percent of patients is not a sample, for data collection purposes, CMS would only collect data on the group practice's patients to which the EHR measures apply. Therefore, even though a group practice would report on 100 percent of patients to which the measure applies, not all of the EHR measures would necessarily apply to all of the group practice's patients. Since the group practice is then only providing information on its applicable patients, we believe the proposed EHR reporting criteria would still meet the statistical sampling model requirement. We invite public comment on the proposed criteria for satisfactory reporting of individual measures by group practices via claims, registry, or EHR for the 2013 and 2014 incentives.

A summary of the proposed criteria for satisfactory reporting for group practices selected

to participate in the GPRO for the 2013 and 2014 incentives is specified in Tables 27 and 28:

**TABLE 27: Proposed Criteria for Satisfactory Reporting of Data on PQRS Quality Measures via the GPRO for the 2013 Incentive**

| Reporting Period | Reporting Mechanism | Group Practice Size | Proposed Reporting Criterion |
|---|---|---|---|
| 12-month (Jan 1 — Dec 31) | GPRO Web-Interface | 25-99 eligible professionals | Report on all measures included in the web interface in Table 35; AND<br>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. |
| 12-month (Jan 1 — Dec 31) | GPRO Web-Interface | 100+ eligible professionals | Report on all measures included in the web interface in Table 35; AND<br>Populate data fields for the first 411 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 411, then report on 100 percent of assigned beneficiaries. |
| 12-month (Jan 1 — Dec 31)* | Claims | 2-99 eligible professionals | Report at least 3 measures, AND<br>Report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies.<br>Measures with a 0 percent performance rate will not be counted. |
| 12-month (Jan 1 — Dec 31) | Qualified Registry | 2-99 eligible professionals | Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| 12-month (Jan 1 — Dec 31) | Direct EHR product | 2-99 eligible professionals | Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals for reporting those CQMs (75 FR 44398 through 44411).<br>Option 2: Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| 12-month (Jan 1 — Dec 31) | EHR data submission vendor | 2-99 eligible professionals | Option 1: Eligible professionals in a group practice must report on three Medicare EHR Incentive Program core or alternate core measures, plus three additional measures. The EHR Incentive Program' core, alternate core, and additional measures can be found in Table 6 of the EHR Incentive Program's Stage 1 final rule (75 FR 44398) or in Tables 32 and 33 of this section. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for eligible professionals for reporting those CQMs (75 FR 44398 through 44411).<br><br>Option 2: Report at least 3 measures, AND<br>Report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the |

| Reporting Period | Reporting Mechanism | Group Practice Size | Proposed Reporting Criterion |
|---|---|---|---|
| | | | reporting period to which the measure applies.<br>Measures with a 0 percent performance rate will not be counted. |

* Subject to the measure applicability validation (MAV) process.

**Table 28: Proposed Criteria for Satisfactory Reporting of Data on PQRS Quality Measures via the GPRO for the 2014 Incentive**

| Reporting Period | Reporting Mechanism | Group Practice Size | Proposed Reporting Criterion |
|---|---|---|---|
| 12-month (Jan 1 — Dec 31) | GPRO Web-Interface | 25-99 eligible professionals | Report on all measures included in the web interface in Table 35; AND<br>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. |
| 12-month (Jan 1 — Dec 31) | GPRO Web-Interface | 100+ eligible professionals | Report on all measures included in the web interface in Table 35; AND<br>Populate data fields for the first 411 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 411, then report on 100 percent of assigned beneficiaries. |
| 12-month (Jan 1 — Dec 31)* | Claims | 2-99 eligible professionals | Report at least 3 measures, AND<br>Report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies.<br>Measures with a 0 percent performance rate will not be counted. |
| 12-month (Jan 1 — Dec 31) | Qualified Registry | 2-99 eligible professionals | Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| 12-month (Jan 1 — Dec 31) | Direct EHR product | 2-99 eligible professionals | Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness.<br><br>Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33.<br><br>Option 2: Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |
| 12-month (Jan 1 — Dec 31) | EHR data submission vendor | 2-99 eligible professionals | Option 1a: Select and submit 12 clinical quality measures available for EHR-based reporting from Tables 32 and 33, including at least 1 measure from each of the following 6 domains – (1) patient and family engagement, (2) patient safety, (3) care coordination, (4) population and public health, (5) efficient use of healthcare resources, and (6) clinical process/effectiveness. |

| Reporting Period | Reporting Mechanism | Group Practice Size | Proposed Reporting Criterion |
|---|---|---|---|
| | | | Option 1b: Submit 12 clinical quality measures composed of all 11 of the proposed Medicare EHR Incentive Program core clinical quality measures specified in Tables 32 and 33 plus 1 menu clinical quality measure from Tables 32 and 33.<br><br>Option 2: Report at least 3 measures, AND<br>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.<br>Measures with a 0 percent performance rate will not be counted. |

* Subject to the measure applicability validation (MAV) process.

c. Proposed Analysis of the Criteria for Satisfactory Reporting for the 2013 and 2014 Incentives

For the proposed criteria for satisfactory reporting for the 2013 and 2014 incentives described in this section, we propose that eligible professionals and group practices may not combine different satisfactory reporting criteria under different reporting mechanisms to meet the requirements of satisfactory reporting for the 2013 and 2014 incentives. For example, an eligible professional may not meet the requirements for the 2013 incentive by reporting on 2 applicable PQRS quality measures via claims and 1 applicable PQRS quality measure via qualified registry, because the eligible professional did not meet the criteria for satisfactory reporting under at least one reporting mechanism. Similarly, a group practice would be required to select a single reporting mechanism for the entire group practice. For example, for a group practice consisting of 4 eligible professionals, the group practice would not be able to meet the requirements for the 2013 incentive by reporting 2 individual measures via claims and 1 measure via the direct EHR submission method.

For individual eligible professionals and group practices reporting on individual measures and/or measures groups, please note that, although an eligible professional or group practice could meet more than one criterion for satisfactory reporting, only one incentive payment will be made to the eligible professional or group practice. For example, if an eligible professional meets the criteria for satisfactory reporting of individual measures via claims and measures

groups via claims for the 2013 incentive, the eligible professional would nonetheless only be entitled to one incentive payment. CMS would consider the eligible professional to be incentive eligible under whichever reporting criterion yields the greatest bonus. We invite public comment on our proposed analysis of the criteria for satisfactory reporting for the 2013 and 2014 incentives.

5. Proposed Criteria for Satisfactory Reporting for the Payment Adjustments

Section 1848(a)(8) of the Social Security 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. The applicable percent for 2015 is 98.5 percent. For 2016 and subsequent years, the applicable percent is 98.0 percent.

This section contains the proposed criteria for satisfactory reporting for purposes of the 2015 and 2016 payment adjustments for eligible professionals and group practices, as well as some discussion of what we are considering for the payment adjustments for 2017 and beyond.

As stated previously, the majority of eligible professionals currently are not participating in the PQRS. Yet, the payment adjustment will apply to all eligible professionals who are not satisfactory reporters during the reporting period for the year. Therefore, in implementing the PQRS payment adjustment, we seek to achieve two overarching policy goals. First, and foremost, we seek to increase participation in the PQRS and to implement the payment adjustment in a manner that will allow eligible professionals who have never participated in the program to familiarize themselves with the program. Second, we seek to align the reporting

requirements under the PQRS with the quality reporting requirements being proposed for the physician value-based payment modifier discussed in section III.K of this proposed rule.

a. Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices using the Claims, Registry, EHR, and GPRO web-interface Reporting Mechanisms

This section contains our proposals for the criteria for satisfactory reporting for the 2015 and 2016 payment adjustments using the claims, registry, EHR-based, and GPRO web-interface reporting mechanisms. First, we propose that for purposes of the 2015 and 2016 payment adjustments (which would be based on data reported during 12 and 6-month reporting periods that fall within 2013 and 2014, respectively), an eligible professional or group practice would meet the requirement to satisfactorily report data on quality measures for covered professional services for the 2015 and 2016 payment adjustments by meeting the requirement for satisfactory reporting for the 2013 and 2014 incentives respectively. That is, we are proposing the exact same criteria for satisfactory reporting for the 2015 and 2016 payment adjustments that we are proposing for the 2013 and2014 incentives, described in Tables 25 and 26, with the exception of one additional alternative criterion. Since we have already proposed satisfactory reporting criteria for the 2013 and 2014 incentives and the reporting periods for the respective 2013 and 2014 incentives and 2015 and 2016 payment adjustments coincide, we believe it is appropriate that the proposed criteria for the 2013 and 2014 respective incentives apply to satisfy the satisfactory reporting requirements for the 2015 and 2016 payment adjustments, respectively. Please note that these proposed criteria for the 2013 and 2014 PQRS incentives are the only criteria we are proposing to establish for the respective 2015 and 2016 PQRS payment adjustments for group practices using the GPRO web-interface.

With respect to individual eligible professionals also participating in the EHR Incentive

Program, it is our intention to align our proposed criteria for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments with the criteria for meeting the CQM component of meaningful use applicable during the 2015 and 2016 PQRS payment adjustment reporting periods. For eligible professionals participating in PQRS and the EHR Incentive Program using a direct EHR product or EHR data submission vendor that is CEHRT, please note that since we are proposing to align our proposed EHR criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives with the proposed criteria for meeting the CQM component of meaningful use for CYs 2013 and 2014,if these proposals are established and we meet our goal of aligning the two programs, we note that an eligible professional meeting the CQM component of meaningful use during the PQRS 2015 and 2016 payment adjustment reporting periods using a direct EHR product or EHR data submission vendor that is CEHRT would be able to meet the requirements for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments by submitting a single set of data.

As a result of the overarching goals we have articulated above about encouraging participation and concern about eligible professionals' familiarity and experience with the program, we propose the following alternative criteria for satisfactory reporting during the 12-month reporting periods for the 2015 and 2016 payment adjustments for eligible professionals and group practices: report 1 measure or measures group using the claims, registry, or EHR-based reporting mechanisms. We understand that this particular proposed alternative criterion for satisfactory reporting are significantly less stringent that the satisfactory reporting criteria we have proposed for the 2013 and 2014 incentives. However, we stress that we are proposing less stringent criteria only to ease eligible professionals and group practices who have not previously participated in PQRS into reporting. We note that we are only proposing these criteria for the 2015 and 2016 payment adjustments. As indicated in section III.G.5.c., for 2017 and beyond, we

anticipate eliminating these alternative proposed criteria and establishing criteria that more closely resembles the proposed satisfactory reporting criteria for the 2013 and 2014 incentives.

With respect to group practices, section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration, we note that this proposed reporting criteria meets this standard, as the group practice would decide on which sample of patients to report. In these proposed criteria, the group practice would select the sample number, meaning the group could choose to report on all applicable patients or a certain number of patients to which the particular measure applied. Please note that, although the group practice may choose the sample, we anticipate that the sample the group practice selects would represent a sufficient picture of the beneficiaries the group practice sees. We invite public comment on the proposed criteria for satisfactory reporting for the 2015 and 2016 payment adjustments for eligible professionals and group practices using the claims, registry, EHR-based reporting mechanisms.

b. Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices using the Administrative Claims-based Reporting Mechanism

(1) Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices using the Administrative Claims-based Reporting Mechanism

Unlike the traditional PQRS claims-based reporting mechanism, the proposed administrative claims-based reporting mechanism does not require an eligible professional to submit quality data codes (QDCs) on Medicare Part B claims. Rather, using the administrative claims-based reporting mechanism only requires that an eligible professional or group practice submit Medicare claims to CMS. Since CMS, rather than the eligible professional or group

practice, is performing the analysis and collecting the data provided in an eligible professional's or group practice's Medicare claims for an eligible professional's or group practice's Medicare beneficiaries, we believe it is appropriate to propose a reporting threshold that is more stringent than that proposed for the 2013 and 2014 incentives that use traditional PQRS reporting mechanisms. Therefore, we propose the following criteria for satisfactory reporting for the 12-month reporting periods for the 2015 and 2016 payment adjustments for eligible professionals and group practices using the administrative claims-based reporting mechanism: Report ALL measures in Table 63 for 100 percent of the cases in which the measures apply.

Section 1848(m)(3)(C) requires that the criterion for group reporting use a statistical sampling model, such as the model used in the PGP demonstration. We note that, although these criteria depart from the model used in the PGP demonstration, similar to our arguments for the satisfactory reporting criteria we are proposing for group practices using the claims, registry, and EHR-based reporting mechanisms, we believe that these criteria still meet the statistical sampling model requirement in that the group practices would still be required to report the measures on a sample of their patients. We understand that, with these proposed criteria, the group practice provides claims data to CMS on 100 percent of its patients for which the measure applies. We note that although reporting on 100 percent of patients is not a sample, for data collection purposes, CMS would only collect data on the group practice's patients to which the administrative claims measures apply. Therefore, even though a group practice who sees 100 patients during the applicable PQRS payment adjustment reporting period would report on 100 percent of patients to which the measure applies, not all of the proposed administrative claims measures would necessarily apply to all of the group practice's patients. Since the group practice is then only providing information on its applicable patients, we believe these reporting criteria would still meet the statistical sampling model requirement. We invite public comment on these

proposed criteria.

When considering proposals for reporting criteria for the 2015 and 2016 PQRS payment adjustments, we considered satisfactory reporting options that would encourage eligible professionals and group practices to report for the 2013 and/or 2014 incentives but, should eligible professionals or group practices come up shy of meeting the 2013 and/or 2014 incentive reporting criteria, would still allow an eligible professional to meet the criteria for satisfactory reporting for the 2015 and/or 2016 payment adjustments. In lieu or more lenient satisfactory reporting criteria we proposed for the 2015 and 2016 payment adjustment, e.g. to report at least 1 measure or measures group or to elect the administrative claims-based reporting option, we considered the option of defaulting those eligible professionals who report but fail to meet the criteria for satisfactory reporting using the proposed criteria for the 2013 and/or 2014 incentives to the administrative claims-based reporting option. We would therefore analyze the claims of all eligible professionals who report at least 1 measure under a traditional reporting method during the respective 2015 and 2016 payment adjustment reporting periods under the administrative claims-based reporting option. We considered this proposal because it is our intention to encourage eligible professionals to report PQRS measures using the proposed reporting criteria for the 2013 and 2014 PQRS incentives. However, given our concern about new eligible professionals' familiarity and experience with the program, we believe it is necessary to propose an alternative, less stringent reporting option. We invite public comment on this considered proposal.

c. Proposed Analysis of Eligible Professionals and Group Practices who will be Assessed a PQRS Payment Adjustment

As noted in §414.90(b), an eligible professional is assessed at the TIN/NPI level and a group practice selected to participate in the GPRO is assessed at the TIN level. As there is a 1-

year lapse in time between the end of a proposed respective payment adjustment reporting period and when an eligible professional is expected to receive a PQRS payment adjustment for not meeting the requirements for satisfactory reporting for the respective payment adjustment, we understand that an eligible professional may change his or her TIN/NPIs during this lapse of time. Likewise, a group practice selected to participate in the GPRO may change its TIN during this lapse in time. We believe this raises issues with regard to the subsequent application of the payment adjustment and concerns about the potential for abuse (e.g., "gaming the system"). Accordingly, we invite public comment this issue, including what parameters, if any, CMS should impose regarding the changes in TIN/NPIs and compositions of group practices with regard to the payment adjustment.

d. Criteria for Satisfactory Reporting for the Payment Adjustments for 2017 and Beyond for Eligible Professionals and Group Practices

We have stressed the importance of allowing eligible professionals and group practices who are new to the program to gain familiarity with PQRS's reporting requirements. However, we note that, as we move towards the sole implementation of payment adjustments (which would serve as the reporting period for the 2017 payment adjustment), it is our intention that eligible professionals would be expected to meet reporting criteria that more closely align to the reporting criteria that we have proposed for the 2014 incentives above. It is our expectation that in two years' time, eligible professionals who are new to PQRS would have enough familiarity with the program that CMS could reasonably expect a majority of participating eligible professionals to meet the requirements that are identical or very similar to those that have been required for incentive payment purposes. We invite public comment on goals for future criteria for satisfactory reporting we may require under the program for the 2017 payment adjustment that are identical or similar to the criteria we have proposed for the 2014 incentive payments.

We also invite commenters to provide alternative criteria for us to consider in future rulemaking for the payment adjustments for 2017 and beyond.

6. PQRS Quality Measures for 2013 and Beyond

a. Statutory Requirements for the Selection of Proposed PQRS quality measures for 2013 and Beyond

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 subsection 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, as amended by adding section 3014 of the Patient Protection and Affordable Care Act (PPACA), requires that the entity with a contract with the Secretary under subsection 1890(a) of the Act (currently that, is the NQF) establish a multi-stakeholder group that would provide for a transparent process for selecting quality measures, such as the quality measures selected for reporting under the PQRS. Pursuant to section 3014 of Affordable Care Act, the NQF created the Measure Applications Partnership. Section 1890(b)(7)(B) requires that the Secretary establish a pre-rulemaking process whereby the multi-stakeholder group will provide input to the Secretary on the selection of quality measures. To receive input from the Measures Applications Partnership, we submitted all the measures we are proposing in this section with the exception of the administrative claims measures that we are incorporating to align with the Value-Based Modifier and the measures that we are incorporating to align with the Medicare Shared Savings Program specified in Tables 29 through 62. The list of measures the Measures Application Partnership have considered for 2012 are available at http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.

b. Other Considerations for the Selection of Proposed PQRS quality measures for 2013 and Beyond

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. 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.

On October 7, 2011, we ended a Call for Measures that solicited new measures for possible inclusion in the PQRS for 2013 and beyond. During the Call for Measures, we solicited measures that were either consistent with section 1848(k)(2)(C) of the Act or fell under the exception specified in section 1848(k)(2)(C)(ii) of the Act. Although the deadline to submit

measures for consideration for the 2013 PQRS program year has ended, we invite public comment on future considerations related to the selection of new PQRS quality measures.

c. Proposed PQRS Quality Measures

This section focuses on the proposed PQRS individual Measures available for reporting via claims, registry, and/or EHR-based reporting for 2013 and beyond. To align with the proposed measure domains provided in the EHR Incentive Program (77 FR 13743), we classify all proposed measures against six domains based on the National Quality Strategy's six priorities, as follows:

(1) Patient and Family Engagement. 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) 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.

(4) Population and Public Health. These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served and are

especially focused on the leading causes of mortality. 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) Efficient Use of Healthcare Resources. 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) Clinical Processes/Effectiveness. 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 2012, 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 substantially change the nature of the

measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. 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 this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the PQRS in a manner that we consider to not substantially 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. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the CMS QualityNet Website at https://www.QualityNet.org. We would provide sufficient lead time for [insert applicable party; i.e. hospitals, LTCHs, etc.] to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF – endorsed [insert name of applicable program] 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 invite public comment on this proposal.

To receive more information on the proposed measures contained in this section, including the measure specifications for these proposed measures, please contact the respective measure owners. Contact information for the measure owners of these proposed PQRS measures

is available at the PQRS Website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

(1) Proposed PQRS Individual Core Measures Available for Claims, Qualified Registry, and EHR-based Reporting for 2013 and Beyond

In 2011, the Department of Health and Human Services (HHS) started the Million Hearts Initiative, which is an initiative to prevent 1 million heart attacks and strokes in five years. We are dedicated to this initiative and seek to encourage eligible professionals to join in this endeavor. Therefore, based on our desire to support the Million Hearts initiative and maintain our focus on cardiovascular disease prevention, we are proposing the following proposed individual PQRS Core Measures specified in Table 29 for 2013 and beyond. Please note that these measures are the same measures we finalized under the 2012 PQRS in the CY 2012 Medicare PFS final rule (76 FR 73345).

**TABLE 29: Proposed PQRS Individual Core Measures for 2013 and Beyond**

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0064/ 2 | | Clinical Process/ Effectiveness | **Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** 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 | X | X | X | | X | HITECH Million Hearts |
| 0068/ 204 | | Clinical Process/ Effectiveness | **Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients aged 18 years and older | NCQA | X | X | X | X | X | HITECH ACO Million Hearts |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic | | | | | | | |
| 0028/ 226 | | Population /Public Health | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI | X | X | X | X | X | HITECH ACO Million Hearts |
| 0018/ 236 | | Clinical Process/ Effectiveness | **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 | HITECH ACO Million Hearts |
| 0075/ 241 | | Clinical Process/ Effectiveness | **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 | X | X | X | X | X | HITECH ACO Million Hearts |
| N/A/ 316 | | Clinical Process/ Effectiveness | **Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL:** Percentage of patients aged 20 through 79 years | CMS/ QIP | | | X | | | HITECH Million Hearts |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | whose risk factors* have been assessed and a fasting LDL test has been performed<br>*There are three criteria for this measure based on the patient's risk category.<br>1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent<br>2. Moderate Level of Risk: Multiple (2+) Risk Factors<br>3. Lowest Level of Risk: 0 or 1 Risk Factor | | | | | | | |
| N/A/ 317 | | Population /Public Health | **Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 and older who are screened for high blood pressure | CMS/ QIP | X | X | X | X | X | HITECH ACO Million Hearts |

*Measures that can be reported using the GPRO web interface.
¥ Titles and descriptions in this table are aligned with the proposed 2013 Physician Quality Reporting System Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

Please note that, although we are proposing that the measures in Table 29 serve as core PQRS quality measures, we are not proposing to require that eligible professionals report on these proposed PQRS core measures. We invite public comment on the proposed PQRS core measures for 2013 and beyond.

(2) Proposed PQRS quality measures Available for Reporting via the Claims, Qualified Registry, EHR, and GPRO Web-Interface Reporting Mechanisms for 2013 and Beyond

This section contains our proposals for individual PQRS quality measures for 2013 and beyond. Please note that, in large part, we are proposing to retain most of the quality measures we finalized for reporting for the 2012 PQRS (76 FR 42865 through 42872). However, in 2013 and 2014, we are proposing to include new measures, as well as remove measures that were available for reporting under the 2012 PQRS (not re-propose certain measures for 2013 and beyond). Table 30 specifies the measures we are proposing to be available for reporting under the PQRS for 2013 and beyond.

**TABLE 30: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR and/or the GPRO Web-Interface for 2013 and Beyond That Were NOT Available for Reporting under the 2012 PQRS**

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| TBD / TBD | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure):** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke who arrive at the hospital within 4.5 hours of time last known well who were considered for t-PA administration | AMA-PCPI | X | X | | | | |
| TBD / TBD | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure):** Percentage of all patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA, for whom t-PA was initiated within three hours of time last known | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | well | | | | | | | |
| 0729 / TBD | Clinical Process/ Effectiveness | **Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: A1c < 8.0%, LDL < 100 mg/dL, blood pressure < 140/90 mmHg, tobacco non-user and for patients with a diagnosis of ischemic vascular disease daily aspirin use unless contraindicated | MNCM | | | | X | | ACO |
| 0658 / TBD | Care Coordination | **Endoscopy and Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report | AMA-PCPI | X | X | | | | |
| 0493 / TBD | Care Coordination | **Participation by a Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves:<br>a. Physician or other clinician submits standardized data elements to registry<br>b. Data elements are applicable to consensus endorsed quality measures<br>c. Registry measures shall include at | CMS/ QIP | X | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures.<br>d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians.<br>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.<br>f. Registry may provide feedback directly to the provider's local registry if one exists | | | | | | | |
| 0670 / TBD | Efficient Use of Healthcare Resources | **Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac computed tomography angiography (CCTA), or cardiovascular magnetic resonance (CMR) performed in low risk surgery patients for preoperative evaluation | ACC | | X | | | | |
| 0671 / TBD | Efficient Use of Healthcare | **Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary** | ACC | | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | Resources | **Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and stress echo performed routinely after percutaneous cardiology intervention (PCI), with reference to timing of test after PCI and symptom status | | | | | | | |
| 0672 / TBD | Efficient Use of Healthcare Resources | **Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asyptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients for intial detection and risk assessment | ACC | | X | | | | |
| TBD / TBD | Clinical Process/ Effectiveness | **Adult Major Depressive Disorder: Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up:** Percentage of medical records of patients aged 18 years and older with a diagnosis of MDD and a diagnosed co-morbid condition being treated by another physician with communication to the other physician treating the co-morbid condition | AMA-PCPI | | X | | | | |
| TBD / | Care Coordina | **Coordination of Care of Patients with Co-Morbid Conditions -** | AMA-PCPI | | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| TBD | tion | **Timely Follow-Up (Paired Measure):** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a diagnosed co-morbid condition with communication to another physician treating the co-morbid condition who have a response from the other physician within 45 days of original communication OR who have a follow-up attempt within 60 days of original communication by the physician treating MDD to elicit a response from the other physician | | | | | | | |
| 1525 / TBD | Patient Safety | **Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 and older with nonvalvular AF or atrial flutter at high risk for thromboembolism, according to CHADS2 risk stratification, who were presecribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism during the 12-month reporting period | AMA | X | X | | | | HITECH |
| TBD / TBD | Clinical Process/ Effectiveness | **Pediatric End-Stage Renal Disease Measure (AMA/ASPN): Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of end-stage renal disease | AMA/ ASPN | X | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist | | | | | | | |
| 1667 / TBD | Clinical Process/ Effectiveness | **Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL | AMA | X | X | | | | |

*Measures that can be reported using the GPRO web interface.
[†]These measures can only be reported by participants using the GPRO. They are not available for reporting for individual Eligible Professionals using this reporting method.
¥ Titles and descriptions in this table may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

Although we are proposing to add measures that were not available for reporting under the 2012 PQRS, we note that we are not proposing to retain certain measures from the 2012 PQRS. For reference, in Table 31 we list 14 measures from the 2012 PQRS that we are not proposing for the 2013 PQRS.

**TABLE 31: Measures Included in the 2012 PQRSs Measure Set that are Not Proposed to be Included in the Physician Quality Reporting Program Measure Set for 2013 and Beyond**

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | CMS-Selected EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0246/ 10 | Clinical Process/ Effective ness | **Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports:** Percentage of final reports for CT or MRI studies of the brain performed either:<br>• In the hospital within 24 hours of arrival, OR<br>• In an outpatient imaging center to confirm initial diagnosis of stroke, transient ischemic attack (TIA) or intracranial hemorrhage<br>For patients aged 18 years and older with either a diagnosis of ischemic stroke, TIA or intracranial hemorrhage OR at least one documented symptom consistent with ischemic stroke, TIA or intracranial hemorrhage that includes documentation of the presence or absence of each of the following: hemorrhage, mass lesion and acute infarction | AMA-PCPI/ NCQA | X | X | | | | HITECH |
| 0094/ 57 | Clinical Process/ Effective ness | **Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with oxygen saturation documented and reviewed | AMA-PCPI/ NCQA | X | X | | | X | |
| 0095/ 58 | Clinical Process/ Effective | **Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Mental** | AMA-PCPI/ NCQA | X | X | | | X | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | CMS-Selected EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | ness | **Status:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with mental status assessed | | | | | | | |
| AQA adopted/ 92 | Clinical Process/ Effectiveness | **Acute Otitis Externa (AOE): Pain Assessment:** Percentage of patient visits for those patients aged 2 years and older with a diagnosis of AOE with assessment for auricular or periauricular pain | AMA-PCPI | X | X | | | | |
| 0488/ 124 | Care Coordination | **Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR):** Documents whether provider has adopted and is using health information technology. To report this measure, the eligible professional must have adopted and be using a certified, Physician Quality Reporting System qualified or other acceptable EHR system | CMS/ QIP | X | X | | | | |
| 0466/ 158 | Clinical Process/ Effectiveness | **Carotid Endarterectomy: Use of Patch During Conventional Carotid Endarterectomy:** Percentage of patients aged 18 years and older undergoing conventional (non-eversion) carotid endarterectomy (CEA) who undergo patch closure of the arteriotomy | SVS | X | X | | | | |
| AQA adopted/ 186 | Clinical Process/ Effectiveness | **Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers:** Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who were prescribed compression | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | CMS-Selected EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | therapy within the 12-month reporting period | | | | | | | |
| N/A/ 189 | Care Coordination | **Referral for Otologic Evaluation for Patients with History of Active Drainage from the Ear Within the Previous 90 Days:** Percentage of patients aged birth and older who have disease of the ear and mastoid processes 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 history of active drainage from the ear within the previous 90 days | AQC | X | X | | | | |
| N/A/ 190 | Care Coordination | **Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss:** 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 immediately following an audiologic evaluation that verifies and documents sudden or rapidly progressive hearing loss | AQC | X | X | | | | |
| 0065/ 196 | Clinical Process/ Effectiveness | **Coronary Artery Disease (CAD): Symptom and Activity Assessment:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period for whom there are documented results of an evaluation of level of activity | AMA-PCPI/ ACCF /AHA | | X | | | X | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | CMS-Selected EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | AND an evaluation of presence or absence of anginal symptoms in the medical record | | | | | | | |
| 0082/ 199 | Clinical Process/ Effective ness | **Heart Failure: Patient Education:** Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided with patient education on disease management and health behavior changes during one or more visit(s) within 12 months | CMS/ QIP | | | | X | | |
| 0447/ 212 | Care Coordina tion | **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 | ASHA | | X | | | | |
| 0017/ 235 | Clinical Process/ Effective ness | **Hypertension (HTN): Plan of Care:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN during which either systolic blood pressure ≥ 140 mmHg OR diastolic blood pressure ≥ 90mm Hg, with documented plan of care for hypertension | CMS/ QIP | X | X | | | | |
| 0502/ 253 | Clinical Process/ Effective ness | **Pregnancy Test for Female Abdominal Pain Patients:** Percentage of female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain for whom a pregnancy test ordered | ACEP | X | X | | | | |

*Measures that can be reported using the GPRO web interface.

¥ Titles and descriptions in this table are aligned with the proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

A summary of the measures we are proposing for 2013 and beyond are specified in Table 32. Table 32 specifies our proposals to propose all measures that were available for reporting in PQRS in 2012, with the exception of the measures listed in Table 31, as well as propose new measures specified in Table 30 not available for reporting under PQRS in prior years.

**TABLE 32: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR, or GRPO Web-Interface for 2013 and Beyond**

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0059/ 1 | | Clinical Process/ Effectiveness | **Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0% | NCQA | X | X | X | X | X | HITECH ACO |
| 0064/ 2 | | Clinical Process/ Effectiveness | **Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** 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 | X | X | X | | X | HITECH Million Hearts |
| 0061/ 3 | | Clinical Process/ Effectivenes | **Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** | NCQA | X | X | X | | X | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) | | | | | | | |
| 0081/ 5 | | Clinical Process/ Effectiveness | **Heart Failure: 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 and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy | AMA-PCPI/ ACCF/AHA | | X | X | | X | HITECH |
| 0067/ 6 | | Clinical Process/ Effectiveness | **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 | X | X | X | | X | |
| 0070/ 7 | | Clinical Process/ Effectiveness | **Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI):** Percentage of | AMA-PCPI/ ACCF/AHA | | X | X | | | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy | | | | | | | |
| 0083/ 8 | | Clinical Process/ Effectiveness | **Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy | AMA-PCPI/ ACCF/AHA | | X | X | X | X | HITECH ACO |
| 0105/ 9 | | Clinical Process/ Effectiveness | **Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment:** The percentage of patients 18 years of age and older who were diagnosed with a new episode of major depression, treated with antidepressant medication, and who remained on an antidepressant medication treatment | NCQA | X | X | X | | | HITECH |
| 0086/ 12 | | Clinical Process/ Effectiveness | **Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients | AMA-PCPI/ NCQA | X | X | X | | | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | aged 18 years and older with a diagnosis of POAG who have an optic nerve head evaluation during one or more office visits within 12 months | | | | | | | |
| 0087/ 14 | | Clinical Process/ Effectiveness | **Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of AMD who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| 0088/ 18 | | Clinical Process/ Effectiveness | **Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included | AMA-PCPI/ NCQA | X | X | X | | | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months | | | | | | | |
| 0089/ 19 | | Clinical Process/ Effectiveness | **Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the on-going care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months | AMA-PCPI/ NCQA | X | X | X | | | HITECH |
| 0270/ 20 | | Patient Safety | **Perioperative Care: Timing of Antibiotic Prophylaxis – 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 | AMA-PCPI/ NCQA | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | 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) | | | | | | | |
| 0268/ 21 | | Patient Safety | **Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis | AMA-PCPI/ NCQA | X | X | | | X | |
| 0271/ 22 | | Patient Safety | **Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures):** Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral | AMA-PCPI/ NCQA | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | 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 | | | | | | | |
| 0239/ 23 | | Patient Safety | **Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of 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 | X | X | | | X | |
| 0045/ 24 | | Care Coordination | **Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men** | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a hip, spine or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis | | | | | | | |
| 0092/ 28 | | Clinical Process/ Effectiveness | **Aspirin at Arrival for Acute Myocardial Infarction (AMI):** Percentage of patients, regardless of age, with an emergency department discharge diagnosis of AMI who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay | AMA-PCPI/ NCQA | X | X | | | | |
| 0269/ 30 | | Patient Safety | **Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics:** Percentage of surgical patients aged 18 years and older who receive an | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | anesthetic when undergoing procedures with the indications for prophylactic parenteral antibiotics for whom administration of the prophylactic parenteral antibiotic ordered has been initiated within one hour (if fluoroquinolone or vancomycin, two hours) prior to the surgical incision (or start of procedure when no incision is required) | | | | | | | |
| 0240/ 31 | | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Deep Vein Thrombosis (DVT) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who were administered DVT prophylaxis by end of hospital day two | AMA-PCPI/ NCQA | X | X | | | | |
| 0325/ 32 | | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | transient ischemic attack (TIA) who were prescribed antithrombotic therapy at discharge | | | | | | | |
| 0241/ 33 | | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge | AMA-PCPI/ NCQA | | X | | | | |
| 0243/ 35 | | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Screening for Dysphagia:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who receive any food, fluids or medication by mouth (PO) for whom a dysphagia screening was performed prior to PO intake in accordance with a dysphagia screening tool approved by the | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | institution in which the patient is receiving care | | | | | | | |
| 0244/ 36 | | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage for whom occupational, physical, or speech rehabilitation services were ordered at or prior to inpatient discharge OR documentation that no rehabilitation services are indicated at or prior to inpatient discharge | AMA-PCPI/ NCQA | X | X | | | | |
| 0046/ 39 | | Clinical Process/ Effectiveness | **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 | X | X | X | | X | |
| 0048/ 40 | | Clinical Process/ Effectivenes | **Osteoporosis: Management Following Fracture of Hip, Spine** | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | **or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed | | | | | | | |
| 0049/ 41 | | Clinical Process/ Effectiveness | **Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| 0134/ 43 | | Clinical Process/ Effectiveness | **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 using an IMA graft | STS | X | X | | | X | |
| 0236/ 44 | | Clinical Process/ | **Coronary Artery Bypass Graft (CABG):** | CMS/ QIP | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | **Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received a beta-blocker within 24 hours prior to surgical incision | | | | | | | |
| 0637/ 45 | | Patient Safety | **Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures):** Percentage of cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 48 hours of surgical end time | AMA-PCPI/ NCQA | X | X | | | | |
| 0097/ 46 | | Patient Safety | **Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility:** Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g., hospital, | AMA-PCPI/ NCQA | X | X | | X | | ACO |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | skilled nursing facility, or rehabilitation facility) and seen within 60 days follo wing discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented | | | | | | | |
| 0326/ 47 | | Care Coordinatio n | **Advanced Care Plan:** Percentage of patients aged 65 years and older who have an advanced care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advanced care plan | AMA-PCPI/NC QA | X | X | X | | | |
| 0098/ 48 | | Clinical Process/ Effectivenes s | **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 | AMA-PCPI/ NCQA | X | X | X | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | assessed for the presence or absence of urinary incontinence within 12 months | | | | | | | |
| 0099/ 49 | | Clinical Process/ Effectiveness | **Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence whose urinary incontinence was characterized at least once within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| 0100/ 50 | | Patient and Family Engagement | **Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| 0091/ 51 | | Clinical Process/ Effectiveness | **Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had | AMA-PCPI | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | spirometry evaluation results documented | | | | | | | |
| 0102/ 52 | | Clinical Process/ Effectiveness | **Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator | AMA-PCPI | X | X | | | X | |
| 0047/ 53 | | Clinical Process/ Effectiveness | **Asthma: Pharmacologic Therapy for Persistent Asthma:** Percentage of patients aged 5 through 50 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment | AMA-PCPI/ NCQA | X | X | X | | X | |
| 0090/ 54 | | Clinical Process/ Effectiveness | **Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non- Traumatic Chest Pain:** Percentage of patients aged 40 years and older with an emergency department discharge | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | diagnosis of non-traumatic chest pain who had a 12-lead ECG performed | | | | | | | |
| 0093/ 55 | | Clinical Process/ Effectiveness | **Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope:** Percentage of patients aged 60 years and older with an emergency department discharge diagnosis of syncope who had a 12-lead ECG performed | AMA-PCPI/ NCQA | X | X | | | | |
| 0232/ 56 | | Clinical Process/ Effectiveness | **Emergency Medicine: Community-Acquired Pneumonia (CAP): Vital Signs:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with vital signs documented and reviewed | AMA-PCPI/ NCQA | X | X | | | | |
| 0096/ 59 | | Clinical Process/ Effectiveness | **Emergency Medicine: Community-Acquired Pneumonia (CAP): Empiric Antibiotic:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia with an appropriate empiric antibiotic prescribed | AMA-PCPI/ NCQA | X | X | | | | |
| 0001/ | | Clinical | **Asthma: Assessment of** | AMA- | X | X | X | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 64 | | Process/ Effectiveness | **Asthma Control:** Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated during at least one office visit within 12 months for the frequency (numeric) of daytime and nocturnal asthma symptoms | PCPI/ NCQA | | | | | | |
| 0069/ 65 | | Efficient Use of Healthcare Resources | **Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use:** 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 | NCQA | X | X | | | | HITECH |
| 0002/ 66 | | Efficient Use of Healthcare Resources | **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 | NCQA | X | X | X | | | HITECH |
| 0377/ 67 | | Clinical Process/ | **Hematology: Myelodysplastic** | AMA-PCPI/ | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | **Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia who had baseline cytogenetic testing performed on bone marrow | ASH | | | | | | |
| 0378/ 68 | | Clinical Process/ Effectiveness | **Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy with documentation of iron stores prior to initiating erythropoietin therapy | AMA-PCPI/ ASH | X | X | | | | |
| 0380/ 69 | | Clinical Process/ Effectiveness | **Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in | AMA-PCPI/ ASH | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period | | | | | | | |
| 0379/ 70 | | Clinical Process/ Effectiveness | **Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry:** Percentage of patients aged 18 years and older with a diagnosis of CLL who had baseline flow cytometry studies performed | AMA-PCPI/ ASH | X | X | | | | |
| 0387/ 71 | | Clinical Process/ Effectiveness | **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 | X | X | X | | X | HITECH |
| 0385/ 72 | | Clinical Process/ Effectiveness | **Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients:** Percentage of patients aged 18 years and older with Stage IIIA | AMA-PCPI/ ASCO/NCCN | X | X | X | | X | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period | | | | | | | |
| 0464/ 76 | | Patient Safety | **Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol:** Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed | AMA-PCPI | X | X | | | | |
| 0323/ 81 | | Care Coordinatio n | **Adult Kidney Disease: Hemodialysis Adequacy: Solute:** Percentage of calendar months within a 12-month period during which patients aged 18 | AMA-PCPI | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | years and older with a diagnosis of ESRD receiving hemodialysis three times a week who have a spKt/V ≥ 1.2 | | | | | | | |
| 0321/ 82 | | Care Coordination | **Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months | AMA-PCPI | | X | | | | |
| 0393/ 83 | | Clinical Process/ Effectiveness | **Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C seen for an initial evaluation who had HCV RNA testing ordered or previously performed | AMA-PCPI | | X | | | | |
| 0395/ 84 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | quantitative HCV RNA testing was performed within 6 months prior to initiation of antiviral treatment | | | | | | | |
| 0396/ 85 | | Clinical Process/ Effectiveness | **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 | X | X | | | X | |
| 0397/ 86 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | X | X | | | X | |
| 0398/ 87 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | treatment for whom quantitative HCV RNA testing was performed at no greater than 12 weeks from the initiation of antiviral treatment | | | | | | | |
| 0401/ 89 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | X | X | | | X | |
| 0394/ 90 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | X | X | | | X | |
| 0653/ 91 | | Clinical Process/ Effectiveness | **Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | AOE who were prescribed topical preparations | | | | | | | |
| 0654/ 93 | | Care Coordination | **Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy | AMA-PCPI | X | X | | | | |
| 0391/ 99 | | Clinical Process/ Effectiveness | **Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade | AMA-PCPI/ CAP | X | X | | | | |
| 0392/ 100 | | Clinical Process/ Effectiveness | **Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection | AMA-PCPI/ CAP | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade | | | | | | | |
| 0389/ 102 | | Efficient Use of Healthcare Resources | **Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer | AMA-PCPI | X | X | X | | | HITECH |
| 0390/ 104 | | Clinical Process/ Effectiveness | **Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist) | | | | | | | |
| 0388/ 105 | | Patient Safety | **Prostate Cancer: Three Dimensional (3D) Radiotherapy:** Percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving external beam radiotherapy as a primary therapy to the prostate with or without nodal irradiation (no metastases; no salvage therapy) who receive three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiation therapy (IMRT) | AMA-PCPI | X | X | | | | |
| 0103/ 106 | | Clinical Process/ Effectiveness | **Major Depressive Disorder (MDD): Diagnostic Evaluation:** Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who met the DSM-IV criteria during the visit in which the new diagnosis or recurrent episode was identified during the | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | measurement period | | | | | | | |
| 0104/ 107 | | Clinical Process/ Effectiveness | **Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who had a suicide risk assessment completed at each visit during the measurement period | AMA-PCPI | X | X | | | | |
| 0054/ 108 | | Clinical Process/ Effectiveness | **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 | X | X | | | X | |
| 0050/ 109 | | Patient and Family Engagement | **Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with assessment for function and pain | AMA-PCPI | X | X | | | | |
| 0041/ 110 | | Population/ Public Health | **Preventive Care and Screening: Influenza Immunization:** | AMA-PCPI | X | X | X | X | X | HITECH ACO |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31) | | | | | | | |
| 0043/ 111 | | Clinical Process/ Effectiveness | **Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine | NCQA | X | X | X | X | X | HITECH ACO |
| 0031/ 112 | | Clinical Process/ Effectiveness | **Preventive Care and Screening: Screening Mammography:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer | NCQA | X | X | X | X | X | HITECH ACO |
| 0034/ 113 | | Clinical Process/ Effectiveness | **Preventive Care and Screening: Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening | NCQA | X | X | X | X | X | HITECH ACO |
| 0058/ 116 | | Efficient Use of Healthcare Resources | **Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use:** Percentage of adults aged 18 through 64 years with a diagnosis of acute | NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | bronchitis who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service | | | | | | | |
| 0055/ 117 | | Clinical Process/ Effectiveness | **Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam | NCQA | X | X | X | | X | HITECH |
| 0066/ 118 | | Clinical Process/ Effectiveness | **Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior LVEF < 40% who were prescribed ACE inhibitor or ARB therapy | AMA-PCPI/ ACCF/AHA | | X | | X | | ACO |
| 0062/ 119 | | Clinical Process/ | **Diabetes: Urine Screening:** Percentage of | NCQA | X | X | X | | X | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | patients aged 18 through 75 years with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy | | | | | | | |
| AQA adopted/ 121 | | Clinical Process/ Effectiveness | **Adult Kidney: Disease Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of 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 | X | X | | | X | |
| AQA adopted/ 122 | | Clinical Process/ Effectiveness | **Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care | AMA-PCPI | X | X | | | X | |
| AQA adopted/ | | Clinical Process/ Effectivenes | **Adult Kidney Disease: Patients On Erythropoiesis-** | AMA-PCPI | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 123 | | s | **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 ESA therapy AND have a Hemoglobin level > 12.0 g/dL | | | | | | |
| 0417/ 126 | | Clinical Process/ Effectiveness | **Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months | APMA | X | X | | | | |
| 0416/ 127 | | Clinical Process/ | **Diabetes Mellitus: Diabetic Foot and Ankle** | APMA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | **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 | | | | | | | |
| 0421/ 128 | | Population/ Public Health | **Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18 – 64 years BMI ≥ 18.5 and < 25. | CMS/ QIP | X | X | X | X | X | HITECH ACO |
| 0419/ 130 | | 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 | CMS/ QIP | X | X | | | X | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route | | | | | | | |
| 0420/ 131 | | Population/ Public Health | **Pain Assessment and Follow-Up:** Percentage of 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/ QIP | X | X | | | | |
| 0418/ 134 | | Population/ Public 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 using an age appropriate standardized tool AND follow-up plan documented | CMS/ QIP | X | X | | X | | HITE CH ACO |
| 0650/ | | Clinical | **Melanoma: Continuity** | AMA- | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 137 | | Process/ Effectiveness | **of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes:<br>• A target date for the next complete physical skin exam, AND<br>• A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment | PCPI/ NCQA | | | | | | |
| 0561/ 138 | | Care Coordination | **Melanoma: Coordination of Care:** Percentage of patient visits, regardless of patient age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis | AMA-PCPI/ NCQA | | X | | | | |
| 0566/ 140 | | Clinical Process/ Effectiveness | **Age-Related Macular Degeneration (AMD): Counseling on Antioxidant** | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **Supplement:** Percentage of patients aged 50 years and older with a diagnosis of AMD and/or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD | | | | | | | |
| 0563/ 141 | | Care Coordination | **Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of POAG whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| 0051/ 142 | | Clinical Process/ Effectiveness | **Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-** | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **Counter (OTC) Medications:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with an assessment for use of anti-inflammatory or analgesic OTC medications | | | | | | | |
| 0384/ 143 | | Patient and Family Engagement | **Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified | AMA-PCPI | | X | | | X | HITECH |
| 0383/ 144 | | Patient and Family Engagement | **Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of patient visits, regardless of patient 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 | | X | | | X | |
| 0510/ 145 | | Patient Safety | **Radiology: Exposure Time Reported for Procedures Using Fluoroscopy:** Percentage of final reports for | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | procedures using fluoroscopy that include documentation of radiation exposure or exposure time | | | | | | | |
| 0508/ 146 | | Efficient Use of Healthcare Resources | **Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign" | AMA-PCPI/ NCQA | X | X | | | | |
| 0511/ 147 | | Care Coordination | **Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed | AMA-PCPI | X | X | | | | |
| 0322/ 148 | | Efficient Use of Healthcare Resources | **Back Pain: Initial Visit:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back | NCQA | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain | | | | | | | |
| 0319/ 149 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| 0314/ 150 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| 0313/ 151 | | Clinical Process/ Effectiveness | **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 | NCQA | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | clinician for the episode of back pain | | | | | | | |
| AQA adopted/ 154 | | Patient Safety | **Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| AQA adopted/ 155 | | Care Coordination | **Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months | AMA-PCPI/ NCQA | X | X | | | | |
| 0382/ 156 | | Patient Safety | **Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues | AMA-PCPI | X | X | | | | |
| 0455/ 157 | | Patient Safety | **Thoracic Surgery: Recording of Clinical Stage Prior to Lung Cancer or Esophageal** | STS | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **Cancer Resection:** Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal cancer who had clinical staging provided prior to surgery | | | | | | | |
| 0404/ 159 | | Clinical Process/ Effectiveness | **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 | | X | | | X | |
| 0405/ 160 | | Clinical Process/ Effectiveness | **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/mm3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count | AMA-PCPI/ NCQA | | X | | | X | HITECH |
| 0406/ 161 | | Clinical Process/ Effectiveness | **HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** | AMA-PCPI/ NCQA | | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | 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/mm3 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 | | | | | | | |
| 0407/ 162 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI/ NCQA | | X | | | X | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | of care | | | | | | | |
| 0056/ 163 | | Clinical Process/ Effectiveness | **Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination | NCQA | X | X | X | | X | HITECH |
| 0129/ 164 | | Clinical Process/ Effectiveness | **Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require intubation > 24 hours | STS | | X | | | X | |
| 0130/ 165 | | Clinical Process/ Effectiveness | **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 | | X | | | X | |
| 0131/ 166 | | Clinical Process/ Effectiveness | **Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have | STS | | X | | | X | |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | 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 | | | | | | | |
| 0114/ 167 | | Clinical Process/ Effectiveness | **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 | | X | | | X | |
| 0115/ 168 | | Clinical Process/ Effectiveness | **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 | | X | | | X | |
| 0116/ | | Clinical | **Coronary Artery Bypass** | STS | | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 169 | | Process/ Effectiveness | **Graft (CABG): Antiplatelet Medications at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication | | | | | | | |
| 0117/ 170 | | Clinical Process/ Effectiveness | **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 | | X | | | X | |
| 0118/ 171 | | Clinical Process/ Effectiveness | **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 | | X | | | X | |
| 0259/ 172 | | Clinical Process/ Effectiveness | **Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula:** Percentage of patients aged 18 years and older | SVS | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 4 or 5) or End Stage Renal Disease (ESRD) requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula | | | | | | | |
| AQA adopted/ 173 | | Population/ Public 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 | AMA-PCPI | X | X | X | | X | |
| AQA adopted/ 176 | | Clinical Process/ Effectiveness | **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/ NCQA | X | X | | | X | |
| AQA adopt | | Clinical Process/ | **Rheumatoid Arthritis (RA): Periodic** | AMA-PCPI/ | X | X | | | X | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| ed/ 177 | | Effectiveness | **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 | NCQA | | | | | | |
| AQA adopted/ 178 | | Clinical Process/ Effectiveness | **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/ NCQA | X | X | | | X | |
| AQA adopted/ 179 | | Clinical Process/ Effectiveness | **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/ NCQA | X | X | | | X | |
| AQA adopted/ 180 | | Care Coordination | **Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of RA who have been assessed for | AMA-PCPI/ NCQA | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months | | | | | | | |
| AQA adopted/ 181 | | Patient Safety | **Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with documentation of a screen for elder maltreatment AND documented follow-up plan | CMS/ QIP | X | X | | | | |
| AQA adopted/ 182 | | Care Coordination | **Functional Outcome Assessment:** Percentage of patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool AND documentation of a care plan based on identified functional outcome deficiencies | CMS/ QIP | X | X | | | | |
| 0399/ 183 | | Population/ Public Health | **Hepatitis C: Hepatitis A Vaccination in Patients with HCV:** Percentage of patients aged 18 years and | AMA-PCPI | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | older with a diagnosis of hepatitis C who received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A | | | | | | | |
| 0400/ 184 | | Population/ Public 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 | AMA-PCPI | X | X | | | X | |
| 0659/ 185 | | Care Coordination | **Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy with a history of colonic polyp(s) in a previous colonoscopy, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report | AMA-PCPI/ NCQA | X | X | | | | |
| 0437/ 187 | | Clinical Process/ | **Stroke and Stroke Rehabilitation:** | AHA/ ASA/ TJC | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | **Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well | | | | | | | |
| N/A/ 188 | | 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) | AQC | X | X | | | | |
| 0565/ 191 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI/ NCQA | | X | | | X | HITECH |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | 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 | | | | | | | |
| 0564/ 192 | | Patient Safety | **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 | | X | | | X | HITECH |
| 0454/ 193 | | Patient Safety | **Perioperative Temperature** | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **Management:** Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom *either* active warming was used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time | | | | | | | |
| 0386/ 194 | | Clinical Process/ Effectiveness | **Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of breast, colon, or rectal cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once within 12 months | AMA-PCPI/ ASCO | X | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0507/ 195 | | Clinical Process/ Effectiveness | **Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for all patients, regardless of age, for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement | AMA-PCPI/ NCQA | X | X | | | | |
| 0074/ 197 | | Clinical Process/ Effectiveness | **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 | | X | X | X | X | ACO |
| 0079/ | | Clinical | **Heart Failure: Left** | AMA- | | X | | | X | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 198 | | Process/ Effectiveness | **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 result (of a recent or prior [any time in the past] LVEF assessment) is documented within a 12 month period | PCPI/ ACCF/AHA | | | | | | |
| 0084/ 200 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI/ ACCF/AHA | | | X | | | |
| 0073/ 201 | | Clinical Process/ Effectiveness | **Ischemic Vascular Disease (IVD): Blood Pressure Management Control:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg) | NCQA | X | X | X | | X | HITECH |
| 0068/ 204 | | Clinical Process/ Effectivenes | **Ischemic Vascular Disease (IVD): Use of Aspirin or Another** | NCQA | X | X | X | X | X | HITECH ACO |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | **Antithrombotic:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) with documented use of aspirin or other antithrombotic | | | | | | | Million Hearts |
| 0409/ 205 | | Clinical Process/ Effectiveness | **HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia and gonorrhea screenings were performed at least once since the diagnosis of HIV infection | AMA-PCPI/ NCQA | | X | | | X | |
| 0413/ 206 | | Clinical Process/ Effectiveness | **HIV/AIDS: Screening for High Risk Sexual Behaviors:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for high risk sexual behaviors at least once within 12 months | AMA-PCPI/ NCQA | | X | | | X | |
| 0415/ 207 | | Clinical Process/ Effectiveness | **HIV/AIDS: Screening for Injection Drug Use:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for injection | AMA-PCPI/ NCQA | | X | | | X | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | drug use at least once within 12 months | | | | | | | |
| 0410/ 208 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI/ NCQA | | X | | | X | |
| 0445/ 209 | | Care Coordination | **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 | ASHA | | X | | | | |
| 0449/ 210 | | Care Coordination | **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 | ASHA | | X | | | | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | Communication Measure | | | | | | | |
| 0448/ 211 | | Care Coordination | **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 | ASHA | | X | | | | |
| 0446/ 213 | | Care Coordination | **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 | ASHA | | X | | | | |
| 0444/ 214 | | Care Coordination | **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 | ASHA | | X | | | | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0442/ 215 | | Care Coordination | **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 | ASHA | | X | | | | |
| 0443/ 216 | | Care Coordination | **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 | ASHA | | X | | | | |
| 0422/ 217 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured | FOTO | | X | | | | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0423/ 218 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured | FOTO | | X | | | | |
| 0424/ 219 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured | FOTO | | X | | | | |
| 0425/ 220 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments:** Percentage | FOTO | | X | | | | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured | | | | | | | |
| 0426/ 221 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk- Adjusted Functional Status is measured | FOTO | | X | | | | |
| 0427/ 222 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the elbow, wrist or hand in which the change in their | FOTO | | X | | | | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | Risk-Adjusted Functional Status is measured | | | | | | | |
| 0428/ 223 | | Care Coordination | **Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the neck, cranium, mandible, thoracic spine, ribs, or other general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured | FOTO | | X | | | | |
| 0562/ 224 | | Efficient Use of Healthcare Resources | **Melanoma: Overutilization of Imaging Studies in Melanoma:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma, without signs or symptoms, seen for an office visit during the one-year measurement period, for whom no diagnostic | AMA-PCPI/ NCQA | | X | | | | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | imaging studies were ordered | | | | | | | |
| 0509/ 225 | | Care Coordination | **Radiology: Reminder System for Mammograms:** Percentage of patients aged 40 years and older undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram | AMA-PCPI/ NCQA | X | X | | | | |
| 0028/ 226 | | Population/ Public Health | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI | X | X | X | X | X | HITECH ACO Million Hearts |
| N/A/ 228 | | Clinical Process/ Effectiveness | **Heart Failure (HF): Left Ventricular Function (LVF) Testing:** Percentage of patients 18 years and older with LVF testing performed during the measurement period for patients hospitalized with a principal diagnosis of HF during the reporting | CMS/ QIP | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | period | | | | | | | |
| N/A/ 231 | | Clinical Process/ Effectiveness | **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 | X | X | | | X | |
| N/A/ 232 | | Clinical Process/ Effectiveness | **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 | X | X | | | X | |
| 0457/ 233 | | Clinical Process/ | **Thoracic Surgery: Recording of** | STS | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | **Performance Status Prior to Lung or Esophageal Cancer Resection:** Percentage of patients aged 18 years and older undergoing resection for lung or esophageal cancer who had performance status documented and reviewed within 2 weeks prior to surgery | | | | | | | |
| 0458/ 234 | | Patient Safety | **Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy):** Percentage of thoracic surgical patients aged 18 years and older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy) | STS | | X | | | | |
| 0018/ 236 | | Clinical Process/ Effectiveness | **Hypertension (HTN): Controlling High Blood Pressure:** Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension | NCQA | X | X | X | X | X | HITECH ACO Million Hearts |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | (HTN) and whose BP was adequately controlled (< 140/90 mmHg) | | | | | | | |
| 0013/ 237 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | | | X | | | |
| 0022/ 238 | | Patient Safety | **Drugs to be Avoided in the Elderly:** Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly and/or two different drugs to be avoided in the elderly in the measurement period | NCQA | | | X | | | HITECH |
| 0024/ 239 | | Population/ Public Health | **Weight Assessment and Counseling for Children and Adolescents:** Percentage of children 2 through 17 years of age who had an outpatient visit with a PCP or OB/GYN and who had evidence of BMI percentile documentation, counseling for nutrition and counseling for physical activity during the measurement period | NCQA | | | X | | | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0038/ 240 | | Population/ Public 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 | | | HITE CH |
| 0075/ 241 | | Clinical Process/ Effectiveness | **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 | X | X | X | X | X | HITE CH ACO Million Hearts |
| N/A/ 242 | | Clinical Process/ | **Coronary Artery Disease (CAD): Symptom** | AMA-PCPI/ | | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | Effectiveness | **Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period and with results of an evaluation of level of activity AND an assessment for the presence *or* absence of anginal symptoms, with a plan of care to manage anginal symptoms, if present | ACCF/AHA | | | | | | |
| 0643/ 243 | | Clinical Process/ Effectiveness | **Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the past 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program | ACCF-AHA | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | for the qualifying event/diagnosis who were referred to a CR program | | | | | | | |
| N/A/ 244 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI/ ACCF/AHA | | X | | | | |
| AQA adopted/ 245 | | Clinical Process/ Effectiveness | **Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer <u>without</u> the use of a wound surface culture technique | AMA-PCPI/ NCQA | X | X | | | | |
| AQA adopted/ 246 | | Clinical Process/ Effectiveness | **Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of | AMA-PCPI/ NCQA | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | chronic skin ulcer without a prescription or recommendation to use wet to dry dressings | | | | | | | |
| AQA adopted/ 247 | | Clinical Process/ Effectiveness | **Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current alcohol dependence who were counseled regarding psychosocial AND pharmacologic treatment options for alcohol dependence within the 12-month reporting period | AMA-PCPI/ NCQA | X | X | | | | |
| AQA adopted/ 248 | | Clinical Process/ Effectiveness | **Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12-month reporting period | AMA-PCPI/ NCQA | X | X | | | | |
| N/A/ 249 | | Clinical Process/ Effectivenes | **Barrett's Esophagus:** Percentage of esophageal biopsy reports that | CAP | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | document the presence of Barrett's mucosa that also include a statement about dysplasia | | | | | | | |
| N/A/ 250 | | Clinical Process/ Effectiveness | **Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status | CAP | X | X | | | | |
| N/A/ 251 | | Clinical Process/ Effectiveness | **Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer | CAP | X | X | | | | |
| 0503/ 252 | | Clinical Process/ Effectiveness | **Anticoagulation for Acute Pulmonary Embolus Patients:** Anticoagulation ordered | ACEP | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | for patients who have been discharged from the emergency department (ED) with a diagnosis of acute pulmonary embolus | | | | | | | |
| 0651/ 254 | | Clinical Process/ Effectiveness | **Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location | ACEP | X | X | | | | |
| 0652/ 255 | | Clinical Process/ Effectiveness | **Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED) | ACEP | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| N/A/ 256 | | 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 | SVS | | X | | | | |
| N/A/ 257 | | Clinical Process/ Effectiveness | **Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge | SVS | | X | | | | |
| N/A/ 258 | | Care Coordination | **Rate of Open Elective Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients | SVS | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | undergoing open repair of small or moderate sized abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7) | | | | | | | |
| N/A/ 259 | | Care Coordination | **Rate of Elective Endovascular Aortic Repair (EVAR) of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2) | SVS | | X | | | | |
| N/A/ 260 | | Care Coordination | **Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to | SVS | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | home no later than post-operative day #2 | | | | | | | |
| N/A/ 261 | | Care Coordination | **Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness | AQC | X | X | | | | |
| N/A/ 262 | | Patient Safety | **Image Confirmation of Successful Excision of Image–Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging | ASBS | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy. | | | | | | | |
| N/A/ 263 | | Clinical Process/ Effectiveness | **Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method (excludes open/incisional biopsies) | ASBS | X | X | | | | |
| N/A/ 264 | | Clinical Process/ Effectiveness | **Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure | ASBS | | X | | | | |
| 0645/ 265 | | Care Coordination | **Biopsy Follow-Up:** Percentage of patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by | AAD | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | the performing physician | | | | | | | |
| N/A/ 266 | | Clinical Process/ Effectiveness | **Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies):** Percentage of patient visits with a diagnosis of epilepsy who had the type(s) of seizure(s) and current seizure frequency(ies) for each seizure type documented in the medical record | AAN | X | X | | | | |
| N/A/ 267 | | Clinical Process/ Effectiveness | **Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome:** All visits for patients with a diagnosis of epilepsy who had their etiology of epilepsy or with epilepsy syndrome(s) reviewed and documented if known, or documented as unknown or cryptogenic | AAN | X | X | | | | |
| N/A/ 268 | | Clinical Process/ Effectiveness | **Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12-44 years old) diagnosed with epilepsy who were counseled about epilepsy and how its treatment may affect contraception and pregnancy at least once a year | AAN | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| N/A/ 269 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 270 | | Clinical Process/ Effectiveness | **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 10mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year | AGA | | | | | X | |
| N/A/ 271 | | Clinical Process/ Effectiveness | **Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related** | AGA | | | | | X | |

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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **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 | | | | | | | |
| N/A/ 272 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 273 | | Clinical Process/ Effectiveness | **Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization:** Percentage of patients aged 18 years and older with a diagnosis of | AGA | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | inflammatory bowel disease that had pneumococcal vaccination administered or previously received | | | | | | | |
| N/A/ 274 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 275 | | Clinical Process/ Effectiveness | **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 | AGA | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy | | | | | | | |
| N/A/ 276 | | Clinical Process/ Effectiveness | **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 symptoms, including presence or absence of snoring and daytime sleepiness | AMA-PCPI/ NCQA | | | | | X | |
| N/A/ 277 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 278 | | Clinical Process/ Effectiveness | **Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of | AMA-PCPI/ NCQA | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy | | | | | | | |
| N/A/ 279 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 280 | | Care Coordination | **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 | | | | | X | |
| N/A/ 281 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | | | | | X | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | reviewed at least once within a 12 month period | | | | | | | |
| N/A/ 282 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 283 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 284 | | Clinical Process/ Effectiveness | **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 | AMA-PCPI | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | neuropsychiatric symptoms within a 12 month period | | | | | | | |
| N/A/ 285 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 286 | | Patient Safety | **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 | | | | | X | |
| N/A/ 287 | | Clinical Process/ Effectiveness | **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 driving alternatives within a 12 month period | AMA-PCPI | | | | | X | |
| N/A/ 288 | | Clinical Process/ Effectivenes | **Dementia: Caregiver Education and Support:** Percentage of patients, | AMA-PCPI | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | 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 | | | | | | | |
| N/A/ 289 | | Clinical Process/ Effectivenes s | **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 than 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 | | | | | X | |
| N/A/ 290 | | Clinical Process/ Effectivenes | **Parkinson's Disease: Psychiatric Disorders or Disturbances** | AAN | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
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| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | **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 | | | | | | | |
| N/A/ 291 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 292 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 293 | | Clinical Process/ Effectiveness | **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, | AAN | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | occupational, or speech therapy) discussed at least annually | | | | | | | |
| N/A/ 294 | | Clinical Process/ Effectiveness | **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 | | | | | X | |
| N/A/ 295 | | Clinical Process/ Effectiveness | **Hypertension: Appropriate Use of Aspirin or Other Antiplatelet or Anticoagulant Therapy:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who were prescribed aspirin or other anticoagulant/antiplatelet therapy | ABIM | | | | | X | |
| N/A/ 296 | | Clinical Process/ Effectiveness | **Hypertension: Complete Lipid Profile:** Percentage of patients aged 15 through 90 years old with | ABIM | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | a diagnosis of hypertension who received a complete lipid profile within 24 months | | | | | | | |
| N/A/ 297 | | Clinical Process/ Effectiveness | **Hypertension: Urine Protein Test:** Percentage of patients aged 15 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 | | | | | X | |
| N/A/ 298 | | Clinical Process/ Effectiveness | **Hypertension: Annual Serum Creatinine Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months | ABIM | | | | | X | |
| N/A/ 299 | | Clinical Process/ Effectiveness | **Hypertension: Diabetes Mellitus Screening Test:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months | ABIM | | | | | X | |
| N/A/ 300 | | Clinical Process/ Effectiveness | **Hypertension: Blood Pressure Control:** Percentage of patients aged 15 through 90 years old with a diagnosis of | ABIM | | | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | hypertension who had most recent blood pressure level under control (at goal) | | | | | | | |
| N/A/ 301 | | Clinical Process/ Effectiveness | **Hypertension: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal) | ABIM | | | | | X | |
| N/A/ 302 | | Clinical Process/ Effectiveness | **Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 months | ABIM | | | | | X | |
| N/A/ 303 | | Clinical Process/ Effectiveness | **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 | AAO | | X | | | X | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey | | | | | | | |
| N/A/ 304 | | Patient and Family Engagement | **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 | | X | | | X | |
| 0004/ 305 | | Clinical Process/ Effectiveness | **Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement:** Percentage of adolescent and adult patients with a new episode of alcohol or other drug (AOD) dependence who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial | NCQA | | | X | | | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | hospitalization within 14 days of the diagnosis and who initiated treatment AND who had two or more additional services with an AOD diagnosis within 30 days of the initial visit | | | | | | | |
| 0012/ 306 | | Population/ Public 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 | AMA-PCPI | | | X | | | |
| 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 | AMA-PCPI | | | X | | | |
| 0027/ 308 | | Population/ Public 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.** | NCQA | | | X | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | **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 | | | | | | | |
| 0032/ 309 | | Clinical Process/ Effectiveness | **Cervical Cancer Screening:** Percentage of women aged 21 through 63 years who received one or more Pap tests to screen for cervical cancer | NCQA | | | X | | | HITECH |
| 0033/ 310 | | Population/ Public 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 | | | HITECH |
| 0036/ 311 | | Clinical Process/ Effectiveness | **Use of Appropriate Medications for Asthma:** Percentage of patients aged 5 through 50 years of | NCQA | | | X | | | HITECH |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year | | | | | | | |
| 0052/ 312 | | Efficient Use of Healthcare Resources | **Low Back Pain: Use of Imaging Studies:** Percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of diagnosis | NCQA | | | X | | | HITE CH |
| 0575/ 313 | | Clinical Process/ Effectiveness | **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% | NCQA | | | X | | | |
| N/A/ 316 | | Clinical Process/ Effectiveness | **Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed<br>*There are three criteria | CMS/ QIP | | | X | | | HITE CH Million Hearts |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | for this measure based on the patient's risk category.<br>1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent<br>2. Moderate Level of Risk: Multiple (2+) Risk Factors<br>3. Lowest Level of Risk: 0 or 1 Risk Factor | | | | | | | |
| N/A/ 317 | | Population/ Public Health | **Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 and older who are screened for high blood pressure | CMS/ QIP | X | X | X | X | X | HITECH ACO Million Hearts |
| 0101/ 318 | | Patient Safety | **Falls: Screening for Future Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months | AMA-PCPI/ NCQA | | | | X | | HITECH ACO |
| TBD/ TBD | X | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure):** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke who arrive at the hospital within 4.5 hours of time | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | last known well who were considered for t-PA administration | | | | | | | |
| TBD/ TBD | X | Clinical Process/ Effectiveness | **Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure):** Percentage of all patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA, for whom t-PA was initiated within three hours of time last known well | AMA-PCPI | X | X | | | | |
| 0729/ TBD | X | Clinical Process/ Effectiveness | **Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: A1c < 8.0%, LDL < 100 mg/dL, blood pressure < 140/90 mmHg, tobacco non-user and for patients with a diagnosis of ischemic vascular disease daily aspirin use unless contraindicated | MNCM | | | | X | | ACO |
| 0658/ TBD | X | Care Coordinatio | **Endoscopy and Polyp Surveillance:** | AMA-PCPI | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | n | **Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report | | | | | | | |
| 0493/ TBD | X | Care Coordinatio n | **Participation by a Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves:<br>a. Physician or other clinician submits standardized data elements to registry<br>b. Data elements are applicable to consensus endorsed quality measures<br>c. Registry measures shall include at least two (2) representative NQF consensus endorsed | CMS/ QIP | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | measures for registry's clinical topic(s) and report on all patients eligible for the selected measures.<br>d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians.<br>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.<br>f. Registry may provide feedback directly to the provider's local registry if one exists | | | | | | | |
| 0670/ TBD | X | Efficient Use of Healthcare Resources | **Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echo, cardiac | ACC | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | computed tomography angiography (CCTA), or cardiovascular magnetic resonance (CMR) performed in low risk surgery patients for preoperative evaluation | | | | | | | |
| 0671/ TBD | X | Efficient Use of Healthcare Resources | **Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) and stress echo performed routinely after percutaneous cardiology intervention (PCI), with reference to timing of test after PCI and symptom status | ACC | | X | | | | |
| 0672/ TBD | X | Efficient Use of Healthcare Resources | **Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asyptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion | ACC | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | imaging (MPI), stress echo, cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients for intial detection and risk assessment | | | | | | | |
| TBD/ TBD | X | Clinical Process/ Effectiveness | **Adult Major Depressive Disorder: Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up:** Percentage of medical records of patients aged 18 years and older with a diagnosis of MDD and a diagnosed co-morbid condition being treated by another physician with communication to the other physician treating the co-morbid condition | AMA-PCPI | | X | | | | |
| TBD/ TBD | X | Care Coordination | **Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up (Paired Measure):** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder | AMA-PCPI | | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | | (MDD) and a diagnosed co-morbid condition with communication to another physician treating the co-morbid condition who have a response from the other physician within 45 days of original communication OR who have a follow-up attempt within 60 days of original communication by the physician treating MDD to elicit a response from the other physician | | | | | | | |
| 1525/ TBD | X | Patient Safety | **Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 and older with nonvalvular AF or atrial flutter at high risk for thromboembolism, according to CHADS2 risk stratification, who were presecribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism during the 12-month reporting period | AMA | X | X | | | | HITECH |
| TBD/ TBD | X | Clinical Process/ Effectivenes | **Pediatric End-Stage Renal Disease Measure (AMA/ASPN): Pediatric** | AMA/ASPN | X | X | | | | |

| NQF/ PQRS | New Measure | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| | | s | **Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of end-stage renal disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist | | | | | | | |
| 1667/ TBD | X | Clinical Process/ Effectiveness | **Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL | AMA | X | X | | | | |

*Measures that can be reported using the GPRO web interface.
†These measures can only be reported by participants using the GPRO. They are not available for reporting for individual Eligible Professionals using this reporting method.
¥ Titles and descriptions in this table are aligned with proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

Beginning with reporting periods occurring in 2014, we are proposing the following 45 individual quality measures specified in Table 33 available for reporting under the PQRS:

**TABLE 33: Proposed PQRS Individual Quality Measures Available for Reporting via Claims, Registry, EHR and/or the GPRO Web-Interface for 2014 and Beyond That Were NOT Available for Reporting under the 2012 PQRS**

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| N/A/ TBD | Clinical Process/ Effectiveness | **Preventive Cardiology Composite:**<br>• **Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal<br>• **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<br>• **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 | ABIM | | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | | factor for CHD)<br>• **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<br>• **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<br>• **Counseling for Diet and Physical Activity:** Percentage of patients in the sample who received dietary and physical activity counseling<br>• **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%<br>• **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 | | | | | | | |
| N/A/ TBD | Care Coordination | **Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post | AAHKS /AMA-PCPI | | | | | X | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | | 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 | | | | | | | |
| N/A/ TBD | 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 | AAHKS /AMA-PCPI | | | | | X | |
| N/A/ TBD | 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 | AAHKS /AMA-PCPI) | | | | | X | |
| N/A/ TBD | 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 | AAHKS /AMA-PCPI | | | | | X | |
| TBD/ TBD | Care Coordination | **Radiation Dose Optimization: Utilization of a Standardized Nomenclature for 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 (e.g., RadLex®) and the standardized nomenclature is used in institutions computer systems | AMA-PCPI | | | | | X | |
| TBD/ TBD | Patient Safety | **Radiation Dose Optimization: Cumulative Count of Potential High Dose Radiation Imaging Studies: Computed Tomography** | AMA-PCPI | | | | | X | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | | **(CT) Scans and Cardiac Nuclear Medicine Scans:** Percentage of CT and cardiac nuclear medicine (myocardial perfusion) imaging reports for all patients, regardless of age, that document a count of known previous CT studies (any type of CT) and cardiac nuclear medicine (myocardial perfusion studies) studies that the patient has received in the 12-month period prior to the current study | | | | | | | |
| TBD/ TBD | Patient Safety | **Radiation Dose Optimization: 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 | | | | | X | |
| TBD/ TBD | Care Coordination | **Radiation Dose Optimization: Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for imaging studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available reciprocally to non-affiliated external entities on a secure, media free, searchable basis with patient authorization for at least a 12-month period after the study | AMA-PCPI | | | | | X | |
| TBD/ TBD | Care Coordination | **Radiation Dose Optimization: Search for Prior Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of imaging 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 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 | | | | | X | |
| N/A/ TBD | Clinical Process/ | **Osteoporosis Composite:**<br>• **Status of Participation in Weight-** | ABIM | | X | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | Effectiveness | **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<br>• **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<br>• **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<br>• **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 | | | | | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | | a DXA scan and result documented<br>• **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<br>• **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<br>• **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 | | | | | | | |
| N/A/ TBD | Clinical Process/ Effectiveness | **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 | ABIM | | | | | X | |
| N/A/ TBD | Clinical Process/ Effectiveness | **Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of | ABIM | | | | | X | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | | 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 | | | | | | | |
| N/A/ TBD | 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 | ABIM | | | | | X | |
| N/A/ TBD | Care Coordination | **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 | ABIM | | | | | X | |
| N/A/ TBD | Clinical Process/ Effectiveness | **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 | ABIM | | | | | X | |
| N/A/ TBD | Clinical Process/ Effectiveness | **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 | ABIM | | | | | X | |
| N/A/ | Clinical | **Osteoporosis: Pharmacologic Therapy:** | ABIM | | | | | X | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| TBD | Process/ Effectiveness | 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 | | | | | | | |
| 0060/ TBD | Clinical Process/ Effectiveness | **Hemoglobin A1c Test for Pediatric Patients:** Percentage of pediatric patients with diabetes with a HbA1c test during the measurement period | NCQA | | | X | | | HITECH |
| 0108/ TBD | Clinical Process/ Effectiveness | **ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** The percentage of children 6 to 12 years of age and newly prescribed attention-deficit/hyperactivity disorder (ADHA) medication who had at least three follow-up care visits within a 10-month period, one of which was within 30 days of when the first ADHD medication was dispensed. Two rates are reported.<br>A. Percentage of children with a prescription dispensed for ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase<br>B. Percentage of children with a prescription dispensed for ADHD medication who remained on the 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 | | | HITECH |
| 0110/ TBD | Clinical Process/ Effectiveness | **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 | CQAIMH | | | X | | | HITECH |
| 0403/ TBD | Efficient Use of | **HIV/AIDS: Medical Visits:** Percentage of patients, regardless of age, with a diagnosis | AMA/NCQA | | | X | | | HITECH |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| | Healthcare Resources | of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 60 days between each visit | | | | | | | |
| 0608/ TBD | Clinical Process/ Effectiveness | **Pregnant women that had HBsAg testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy | Ingenix | | | X | | | HITECH |
| 0710/ TBD | Clinical Process/ Effectiveness | **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 | MNCM | | | X | | | HITECH |
| 0712/ TBD | Clinical Process/ Effectiveness | **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 | MNCM | | | X | | | HITECH |
| 1401/ TBD | Population /Public 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 | NCQA | | | X | | | HITECH |
| Not yet endorsed/ TBD | Clinical Process/Effectiveness | **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 | CMS | | | X | | | HITECH |
| Not yet endorsed/ TBD | 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 | | | HITECH |
| Not yet | Patient and Family | **Functional status assessment for knee replacement:** Percentage of patients aged 18 | CMS | | | X | | | HITECH |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO* (web interface)* | Measures Groups | |
| endorsed/ TBD | Engagement | years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments | | | | | | | |
| Not yet endorsed/ TBD | Patient and Family Engagement | **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 | CMS | | | X | | | HITECH |
| Not yet endorsed/ TBD | Patient and Family Engagement | **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 | CMS | | | X | | | HITECH |
| TBD/ TBD | Clinical Process/ Effectiveness | **Children who have dental decay or cavities:** Percentage of children ages 1-17, who have had tooth decay or cavities during the measurement period | MCHB, HRSA | | | X | | | HITECH |
| TBD/ TBD | Clinical Process/ Effectiveness | **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 | University of Minnesota | | | X | | | HITECH |
| TBD/ TBD | Patient Safety | **ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range:** Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period | CMS | | | X | | | HITECH |

*Measures that can be reported using the GPRO web interface.
¥ 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. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

We also note that we are not proposing to include the following 9 measures specified in Table 34 for 2014.

**TABLE 34: Measures that are Not Proposed to be Included in the PQRS Measure Set for 2014 and Beyond**

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description[¥] | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 0388/ 105 | Patient Safety | **Prostate Cancer: Three Dimensional (3D) Radiotherapy:** Percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving external beam radiotherapy as a primary therapy to the prostate with or without nodal irradiation (no metastases; no salvage therapy) who receive three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiation therapy (IMRT) | AMA-PCPI | X | X | | | | |
| AQA adopted/ 173 | Population/ Public 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 | AMA-PCPI | X | X | X | | X | |
| 0084/ 200 | Clinical Process/ Effectiveness | **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 | AMA-PCPI/ACCF/AHA | | | X | | | |
| 0013/ 237 | Clinical Process/ Effectiveness | **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 | AMA-PCPI | | | X | | | |
| 0012/ 306 | Population/ Public 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 | AMA-PCPI | | | X | | | |
| 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 | AMA-PCPI | | | X | | | |
| 0027/ | Population/ | **Smoking and Tobacco Use Cessation,** | NCQA | | | X | | | |

| NQF/ PQRS | National Quality Strategy Domain | Measure Title and Description¥ | Measure Steward | Reporting Mechanism | | | | | Other Quality Reporting Programs |
|---|---|---|---|---|---|---|---|---|---|
| | | | | PQRS Claims | PQRS Qualified Registry | PQRS Qualified EHR | CMS-Selected GPRO (web interface)* | Measures Groups | |
| 308 | Public Health | **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 | | | | | | | |
| 0326/47 | Care Coordination | **Advanced Care Plan:** Percentage of patients aged 65 years and older who have an advanced care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advanced care plan | AMA-PCPI/ NCQA | | | X | | | |
| 0575/ 313 | Clinical Process/ Effectiveness | **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% | NCQA | | | X | | | |

*Measures that can be reported using the GPRO web interface.
¥ Titles and descriptions in this table are aligned with the proposed 2013 EHR Pilot measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

For the 2012 PQRS, the PQRS aligned the measures the program had available for EHR-based reporting with the EHR measures available for reporting under the EHR Incentive Program (76 FR 73364) and CMS proposes to retain those measures for 2013 and beyond. In fact, we are proposing to add or remove measures available for EHR-based reporting that align with what has been proposed for reporting under the EHR Incentive Program for CY 2014 (77

FR 13746). We also intend to align the PQRS measure set with other CMS programs such as the Value-based Modifier and Medicare Shared Savings Program.

As indicated in Tables 29 through 34, we are proposing a total of 264 measures in 2013. Of these proposed measures, we note that 250 of these measures were measures previously established for reporting under the 2012 PQRS. 14 of these proposed measures are newly proposed in 2013. In 2013, we are also proposing to retire 14 measures that were previously established for reporting under the 2012 PQRS. In 2014, we are proposing 34 additional new measures that were not previously established for reporting under the 2012 PQRS and proposing to retire 8 measures that were previously established for reporting under the 2012 PQRS.

For Table 31, which specifies the tables we are not proposing to retain in the PQRS measure set for 2013 and beyond, we are not proposing the following measures for the following reasons:

(1) Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports: We are not proposing that this measure be because the measure is no longer endorsed by NQF and therefore does not satisfy the requirement for PQRS to provide consensus-based quality measures under section 1848(k)(2)(C)(i) of the Act. Although section 1848(k)(2)(C)(ii) of the Act provides an exception to proposing PQRS measures endorsed by the NQF, we are not exercising our authority to use this exception. The measure was not recommended for reporting by the Measure Application Partnership and we agree with the Measure Applications Partnership's (MAP) assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.(2) Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Oxygen

Saturation: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(3) Emergency Medicine: Community-Acquired Pneumonia (CAP): Assessment of Mental Status; Acute Otitis Externa (AOE): Pain Assessment: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(4) Carotid Endarterectomy: Use of Patch During Conventional Carotid Endarterectom: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(5) Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(6) Referral for Otologic Evaluation for Patients with History of Active Drainage from

the Ear Within the Previous 90 Days: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(7) Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx..

(8) Heart Failure: Patient Education; Functional Communication Measure - Motor Speech

(9) Coronary Artery Disease (CAD): Symptom and Activity Assessment: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(10) Pregnancy Test for Female Abdominal Pain Patients: The measure was not recommended for reporting by the MAP and we agree with the MAP's assessment. More information on the MAP's assessment can be found in the "MAP Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking" available at http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

(11) We also decline to propose the measure titled "Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR)" again for the 2013 PQRS because of

our desire to align with the EHR Incentive Program. In addition, we believe that, since we anticipate that most eligible professionals reporting via EHR will also participate in the EHR Incentive Program, we believe it is redundant to have an eligible professional report on whether or not s/he has adopted an EHR.

(12) We are not proposing the measure titled "Hypertension (HTN): Plan of Care" again for 2013 because this measure is being retired by its measure owner.

For the measures we are not proposing to include in PQRS beginning in 2014 in Table 34, we did not propose the Prostate Cancer: Three Dimensional (3D) Radiotherapy; Hypertension (HTN): Blood Pressure Measurement; and Prenatal Care: Anti-D Immune Globulin measures (which are described in detail above in Table 34) for 2014 and beyond because the measures will be retired by its measure owners. We are proposing to retire the measure titled "Preventive Care and Screening: Unhealthy Alcohol Use – Screening" because this measure was recommended for removal from reporting by the Measure Applications Partnership. We are proposing to retire the measure titled "Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation" because evidence suggests that treatments other than Warfarin have proven more effective to treat Heart Failure. Lastly, we did not propose to retain the measures titled "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" and "Advanced Care Plan" for reporting via the EHR-based reporting mechanisms beginning in 2014 to align with the EHR Incentive Program.

As indicated in Tables 30 and 32, we are proposing a total of 212 measures for available for reporting beginning in 2013. Beginning 2014, we are proposing that 210 measures be available for reporting under PQRS. As indicated previously, these proposed measures are

classified under 6 domains.

(1) Patient safety. We are proposing 21 measures under the patient safety domain available for reporting in PQRS beginning in 2013 or 2014. Of these measures, the following 18 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician.
- Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin.
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac).
- Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) Perioperative Care.
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol.
- Prostate Cancer: Three Dimensional (3D) Radiotherapy.
- Documentation of Current Medications in the Medical Record.
- Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol.
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).
- Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics.
- Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).

- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac).
- Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures.
- Perioperative Temperature Management.
- Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy)

The following 3 measures that are classified under the patient safety domain are not NQF-endorsed. For these measures, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for reporting under PQRS for the following reasons:

- Falls: Risk Assessment. We are proposing to include this measure under our authority under section 1848(k)(2)(C)(ii) to adopt a measure endorsed by the AQA alliance.
- Elder Maltreatment Screen and Follow-Up Plan. We are proposing to include this measure under our authority under section 1848(k)(2)(C)(ii) to adopt a measure endorsed by the AQA alliance.
- Image Confirmation of Successful Excision of Image–Localized Breast Lesion.

(2) Patient and Family Engagement. We are proposing 5 measures available for reporting in PQRS under the patient and family engagement domain beginning in 2013 or 2014. Of these measures, the following 4 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Oncology: Medical and Radiation – Plan of Care for Pain.
- Oncology: Medical and Radiation – Pain Intensity Quantified.
- Osteoarthritis (OA): Function and Pain Assessment.
- Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65

Years and Older.

The following measure that is classified under the patient and family engagement domain is not NQF-endorsed: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measures for reporting under PQRS because this measure fills a measure satisfaction gap in the proposed PQRS measure set.

(3) Care Coordination. We are proposing 38 measures available for reporting in PQRS under the care coordination domain beginning in 2013 or 2014. Of these measures, the following 26 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Advanced Care Plan.
- Adult Kidney Disease: Hemodialysis Adequacy: Solute.
- Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute.
- Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of.
- Melanoma: Coordination of Care.
- Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15 percent OR Documentation of a Plan of Care.
- Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy.
- Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use.
- Functional Communication Measure - Spoken Language Comprehension.

- Functional Communication Measure – Attention.
- Functional Communication Measure – Memory.
- Functional Communication Measure – Reading.
- Functional Communication Measure - Spoken Language Expression.
- Functional Communication Measure – Writing.
- Functional Communication Measure – Swallowing.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments.
- Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments.
- Radiology: Reminder System for Mammograms.
- Biopsy Follow-Up.
- Endoscopy and Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.

- Participation by a Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality.

Although the following 3 measures classified under the care coordination domain are not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for reporting in PQRS because these measures have been reviewed by the AQA:

- Functional Outcome Assessment.
- Rheumatoid Arthritis (RA): Glucocorticoid Management.
- Falls: Plan of Care.

The following 8 measures that are classified under the care coordination domain are also not NQF-endorsed. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measures for reporting under PQRS because these measures fills gaps in assessing care coordination in the proposed PQRS measure set.

- Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear.
- Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR).
- Rate of Open Elective Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7)
- Rate of Elective Endovascular Aortic Repair (EVAR) of Small or Moderate Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post- Operative Day #2).
- Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home Post-Operative Day #2).
- Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness.

- CG-CAHPS Clinician/Group Survey.
- Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up (Paired Measure).

(4) Clinical Process/Effectiveness. We are proposing 127 measures available for reporting under the clinical process/effectiveness domain in PQRS beginning in 2013 or 2014. Of these measures, the following 97 measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.
- Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus.
- Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.
- Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Coronary Artery Disease (CAD): Antiplatelet Therapy.
- Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).
- Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment.
- Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation.
- Age-Related Macular Degeneration (AMD): Dilated Macular Examination.
- Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy

- Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care.
- Aspirin at Arrival for Acute Myocardial Infarction (AMI).
- Stroke and Stroke Rehabilitation: Deep Vein Thrombosis (DVT) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage.
- Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy.
- Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge.
- Stroke and Stroke Rehabilitation: Screening for Dysphagia.
- Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered.
- Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.
- Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older.
- Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG: Surgery.
- Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery.
- Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.
- Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older.
- Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.
- Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.

- Asthma: Pharmacologic Therapy for Persistent Asthma.
- Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain.
- Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope.
- Emergency Medicine: Community-Acquired Pneumonia (CAP): Vital Signs.
- Emergency Medicine: Community-Acquired Pneumonia (CAP): Empiric Antibiotic.
- Asthma: Assessment of Asthma Control.
- Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline.
- Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy.
- Hematology: Multiple Myeloma: Treatment with Bisphosphonates.
- Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow CytometryBreast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.
- Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients.
- Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia.
- Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment.
- Hepatitis C: HCV Genotype Testing Prior to Treatment.
- Hepatitis C: Antiviral Treatment Prescribed.
- Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment.
- Hepatitis C: Counseling Regarding Risk of Alcohol Consumption.
- Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy.
- Acute Otitis Externa (AOE): Topical Therapy.
- Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN

Category (Regional Lymph Nodes) with Histologic Grade.

- Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.
- Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients.
- Major Depressive Disorder (MDD): Diagnostic Evaluation.
- Major Depressive Disorder (MDD): Suicide Risk Assessment.
- Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy.
- Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.
- Preventive Care and Screening: Screening Mammography .
- Preventive Care and Screening: Colorectal Cancer Screening.
- Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD.
- Diabetes: Urine Screening.
- Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy .
- Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear.
- Melanoma: Continuity of Care – Recall System:.
- Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement.
- Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications.
- HIV/AIDS: CD4+ Cell Count or CD4+ Percentage.

- HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis.
- HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy.
- HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy.
- Diabetes Mellitus: Foot Exam.
- Coronary Artery Bypass Graft (CABG): Prolonged Intubation.
- Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate.
- Coronary Artery Bypass Graft (CABG): Stroke.
- Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure.
- Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration.
- Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge.
- Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge.
- Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge.
- Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula.
- Stroke and Stroke Rehabilitation: Thrombolytic Therapy.
- Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery.
- Oncology: Cancer Stage Documented.
- Radiology: Stenosis Measurement in Carotid Imaging Reports.
- Coronary Artery Disease (CAD): Lipid Control.
- Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment.
- Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea.

- HIV/AIDS: Screening for High Risk Sexual Behaviors.
- HIV/AIDS: Screening for Injection Drug Use.
- HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis.
- Heart Failure (HF): Left Ventricular Function (LVF) Testing.
- Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection.
- Hypertension (HTN): Controlling High Blood Pressure.
- Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control.
- Cardiac Rehabilitation Patient Referral from an Outpatient Setting.
- Anticoagulation for Acute Pulmonary Embolus Patients.
- Ultrasound Determination of Pregnancy Location for Pregnant Patients withRh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure.
- Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL.

We are proposing 29 measures for inclusion in the PQRS measure set under the clinical process domain in 2013/2014 that are not NQF-endorsed. Although the following 11 measures classified under the clinical domain are not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for reporting in PQRS because these measures have been reviewed by the AQA:

- Adult Kidney: Disease Laboratory Testing (Lipid Profile).
- Adult Kidney Disease: Blood Pressure Management.
- Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL.

- Rheumatoid Arthritis (RA): Tuberculosis Screening.
- Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity.
- Rheumatoid Arthritis (RA): Functional Status Assessment.
- Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis.
- Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers.
- Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers.
- Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence.
- Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence.

The following 18 measures that are classified under the care coordination domain are also not NQF-endorsed. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measures for reporting under PQRS because these measures fill gaps in measuring clinical process in the proposed PQRS measure set.

- Asthma: Tobacco Use: Screening - Ambulatory Care Setting.
- Asthma: Tobacco Use: Intervention - Ambulatory Care Setting.
- Coronary Artery Disease (CAD): Symptom Management.
- Hypertension: Blood Pressure Management.
- Barrett's Esophagus.
- Radical Prostatectomy Pathology Reporting.
- Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients.

- Statin Therapy at Discharge after Lower Extremity Bypass (LEB).
- Preoperative Diagnosis of Breast Cancer.
- Sentinel Lymph Node Biopsy for Invasive Breast Cancer.
- Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies).
- Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome.
- Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy.
- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.
- Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered (Paired Measure).
- Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Administered Initiated (Paired Measure) .
- Adult Major Depressive Disorder: Coordination of Care of Patients with Co-Morbid Conditions - Timely Follow-Up.
- Pediatric End-Stage Renal Disease Measure (AMA/ASPN): Pediatric Kidney Disease: Adequacy of Volume Management.

(5) Population/Public Health. We are proposing 9 measures classified under the population/public health available for reporting in PQRS beginning in 2013 or 2014. Of these measures, the following 7 measures are NQF-endorsed, and therefore, satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Preventive Care and Screening: Influenza Immunization.
- Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
- Pain Assessment and Follow-Up.

- Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan.
- Hepatitis C: Hepatitis A Vaccination in Patients with HCV.
- Hepatitis C: Hepatitis B Vaccination in Patients with HCV.
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

Two proposed PQRS measures in the population/public health domain are not NQF-endorsed. Although the measure "Preventive Care and Screening: Unhealthy Alcohol Use – Screening" classified under the population/public health domain is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure for reporting in PQRS because the measure have been reviewed by the AQA. The measure "Preventive Care and Screening: Screening for High Blood Pressure" classified under the population/public health domain is also not NQF-endorsed. However, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure for reporting under PQRS because the measures fill gaps in assessing population/public health safety in the proposed PQRS measure set.

(6) Efficiency. We are proposing 9 measures available for reporting in PQRS beginning in 2013 or 2014. Of these measures, all measures are NQF-endorsed, and therefore satisfy the requirement that PQRS provide consensus-based measures for reporting under section 1848(k)(2)(C)(i) of the Act.

- Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use.
- Appropriate Testing for Children with Pharyngitis.
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients.

- Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use.
- Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening.
- Melanoma: Overutilization of Imaging Studies in Melanoma.
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluative in Low-Risk Surgery Patients.
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI).
- Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asyptomatic, Low-Risk Patients.

Please note that the titles of the measures may change slightly from CMS program and/or CMS program year based on specifications updates. We intend to continue to work toward complete alignment of measure specifications across programs whenever possible.

(3) Proposed PQRS quality measures Available for Reporting for Group Practices Using the GPRO Web-Interface

We have previously discussed our measure proposals for group practices using the GPRO web-interface. However, in order to emphasize the measures we are proposing for group practices using the GPRO web-interface, we have provided a summary of these proposed measures in the following Table 32. As indicated in Table 35, we are proposing 18 measures for reporting under the PQRS using the GPRO web-interface for 2013 and beyond to align with the quality measures available for reporting under the Medicare Shared Savings Program (76 FR 67890). Please note that the Medicare Shared Savings Program indicates that it established 22 measures. There is a discrepancy because the Medicare Shared Savings Program lists the

Diabetes Composite measure as separate measures, whereas we are referring to the Diabetes Composite measure as one measure in Table 35.

**TABLE 35: Measures Proposed to be Included in the Group Practice Reporting Option (GPRO) Web-Based Interface for 2013 and Beyond¥**

| NQF/ PQRS | GPRO Disease Module | National Quality Strategy Domain | Measure and Title Description | Measure Steward | Other Quality Reporting Programs |
|---|---|---|---|---|---|
| 0059/ 1 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes: Hemoglobin A1c Poor Control:** Percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c > 9.0% | NCQA | HITECH ACO |
| 0083/ 8 | Heart Failure | Clinical Process/ Effectiveness | **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 | HITECH ACO |
| 0097/ 46 | Care Coordination/ Patient Safety | Patient Safety | **Medication Reconciliation:** Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented | AMA-PCPI/ NCQA | HITECH ACO |
| 0041/ 110 | Preventive Care | Population/ Public Health | **Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization | AMA-PCPI | HITECH ACO |
| 0043/ 111 | Preventive Care | Clinical Process/ Effectiveness | **Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine | NCQA | HITECH ACO |
| 0031/ 112 | Preventive Care | Clinical Process/ Effectiveness | **Breast Cancer Screening:** Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer | NCQA | HITECH ACO |
| 0034/ 113 | Preventive Care | Clinical Process/ Effectiveness | **Colorectal Cancer Screening:** Percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer | NCQA | HITECH ACO |
| 0066/ 118 | Coronary Artery Disease | Clinical Process/ Effectivene | **Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left** | AMA-PCPI/ ACCF/ | HITECH ACO |

| NQF/ PQRS | GPRO Disease Module | National Quality Strategy Domain | Measure and Title Description | Measure Steward | Other Quality Reporting Programs |
|---|---|---|---|---|---|
| | | ss | **Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy | AHA | |
| 0421/ 128 | Preventive Care | Population/ Public Health | **Adult Weight Screening and Follow-Up:** Percentage of patients aged 18 years and older with a calculated body mass index (BMI) in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented<br>Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30<br>Age 18-64 years BMI ≥ 18.5 and < 25 | CMS/ QIP | HITECH ACO |
| 0418/ 134 | Preventive Care | Population/ Public Health | **Screening for Clinical Depression:** Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool and follow up plan documented | CMS/ QIP | HITECH ACO |
| 0074/ 197 | Coronary Artery Disease | Clinical Process/ Effectiveness | **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 <100mg/dL, including at a minimum the prescription of a statin | AMA-PCPI/ ACCF/ AHA | HITECH ACO |
| 0068/ 204 | Ischemic Vascular Disease | Clinical Process/ Effectiveness | **Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year | NCQA | HITECH ACO Million Hearts |
| 0028/ 226 | Preventive Care | Population/ Public Health | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI | HITECH ACO Million Hearts |
| 0018/ 236 | Hypertension | Clinical Process/ | **Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of | NCQA | HITECH ACO |

| NQF/ PQRS | GPRO Disease Module | National Quality Strategy Domain | Measure and Title Description | Measure Steward | Other Quality Reporting Programs |
|---|---|---|---|---|---|
| | | Effectiveness | hypertension and whose blood pressure was adequately controlled during the measurement year | | Million Hearts |
| 0075/ 241 | Ischemic Vascular Disease | Clinical Process/ Effectiveness | **Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous transluminal angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had a complete lipid profile performed during the measurement year and whose LDL-C<100 mg/dL | NCQA | HITECH ACO Million Hearts |
| N/A/ 317 | Preventive Care | Population/ Public Health | **Preventive Care and Screening: Screening for High Blood Pressure:** Percentage of patients aged 18 years and older who are screened for high blood pressure | CMS/ QIP | HITECH ACO Million Hearts |
| 0101/ 318 | Care Coordination/ Patient Safety | Patient Safety | **Falls: Screening for Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk (patients are considered at risk for future falls if they have had 2 or more falls in the past year or any fall with injury in the past year) at least once within 12 months | AMA-PCPI/ NCQA | HITECH ACO |
| 0729/ TBD | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure:<br>• A1c < 8.0%<br>• LDL < 100 mg/dL<br>• blood pressure < 140/90 mmHg<br>• tobacco non-user<br>• (for patients with a diagnosis of ischemic vascular disease) daily aspirin use unless contraindicated | MNCM | ACO |

¥ Titles and descriptions in this table are aligned with the proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification.

We note that, due to our desire to align with the measures available for reporting under the Medicare Shared Savings Program, we are proposing not to retain the 13 measures specified in Table 36 for purposes of reporting via the GPRO-web interface beginning in 2013.

**TABLE 36: Measures Included in the 2012 PQRS Group Practice Reporting Option Web-Based Interface that are Not Proposed for Inclusion in the Web-Based Interface Beginning in 2013[¥]**

| NQF/ PQRS | GPRO Disease Module | National Quality Strategy Domain | Measure Title and Description | Measure Steward | Other Quality Reporting Programs |
|---|---|---|---|---|---|
| 0064/ 2 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** 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 | Million Hearts |
| 0061/ 3 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) | NCQA | |
| 0081/ 5 | Heart Failure | Clinical Process/ Effectiveness | **Heart Failure: 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 and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy | AMA-PCPI/ ACCF/AHA | |
| 0067/ 6 | Coronary Artery Disease | Clinical Process/ Effectiveness | **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 | |
| 0102/ 52 | Chronic Obstructive Pulmonary Disease | Clinical Process/ Effectiveness | **Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator | AMA-PCPI | |
| 0055/ 117 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam | NCQA | |
| 0056/ 163 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination | NCQA | HITECH |
| 0079/ 198 | Heart Failure | Clinical Process/ Effectiveness | **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 result (of a recent or prior [any time in the past] LVEF assessment) is documented within a 12 month period | AMA-PCPI/ ACCF/AHA | |
| 0082/ 199 | Heart Failure | Clinical Process/ Effectiveness | **Heart Failure: Patient Education:** Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided with patient education on disease management and health behavior changes during one or more visit(s) within 12 months | CMS/ QIP | |

| NQF/ PQRS | GPRO Disease Module | National Quality Strategy Domain | Measure Title and Description | Measure Steward | Other Quality Reporting Programs |
|---|---|---|---|---|---|
| 0079/ 228 | Heart Failure | Clinical Process/ Effectiveness | **Heart Failure (HF): Left Ventricular Function (LVF) Testing:** Percentage of patients 18 years and older with LVF testing performed during the measurement period for patients hospitalized with a principal diagnosis of HF during the reporting period | CMS/ QIP | |
| 0575/ 313 | Diabetes Mellitus | Clinical Process/ Effectiveness | **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% | NCQA | HITECH |
| 0729/ 314 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Mellitus: Daily Aspirin Use for Patients with Diabetes and Ischemic Vascular Disease** Percentage of patients aged 18 to 75 years of age with diabetes mellitus and ischemic vascular disease with documented daily aspirin use during the measurement year unless contraindicated | MNCM | |
| 0729/ 315 | Diabetes Mellitus | Clinical Process/ Effectiveness | **Diabetes Mellitus: Tobacco Non Use** Percentage of patients with a diagnosis of diabetes who indicated they were tobacco non- users | MNCM | |

¥ Titles and descriptions in this table are aligned with the proposed 2013 PQRS Electronic Health Records (EHR) measure titles, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and PQRS numbers for clarification

In addition to the measures we are proposing in Table 36, we are also proposing to have the following measure available for reporting occurring in 2013 and beyond: CG-CAHPS Clinician/Group Survey: Getting timely care, appointments and information; How well your doctors communicate; Patients rating of doctor; Access to specialists; Health promotion and education; Shared decision making; Courteous and helpful office staff; Care coordination; Between visit communication; Educating patients about medication adherences; and Stewardship of patient resources. We note that this survey measure requires a different form of data collection and analysis than the other proposed measures in the PQRS. Therefore, for this measure only, CMS intends to administer the survey on behalf of the group practices participating in the 2013 PQRS GPRO. In other words, CMS intends to collect the data for this measure on group practices' behalf for CY 2013 reporting periods.

(4) Proposed PQRS measures groups Available for Reporting for 2013 and Beyond

We propose the following 20 measures groups for reporting in the PQRS beginning with reporting periods occurring in 2013: Diabetes Mellitus; Chronic Kidney Disease (CKD); Preventive Care; Coronary Artery Bypass Graft (CABG); Rheumatoid Arthritis (RA); Perioperative Care; Back Pain; Hepatitis C; Heart Failure (HF); Coronary Artery Disease (CAD); Ischemic Vascular Disease (IVD); HIV/AIDS; Asthma; Chronic Obstructive Pulmonary Disease (COPD); Inflammatory Bowel Disease (IBD); Sleep Apnea; Dementia; Parkinson's Disease; Hypertension; Cardiovascular Prevention; and Cataracts. These 20 proposed measures groups were available for reporting under the PQRS in 2012.

Beginning in 2013, we are proposing the oncology measures groups for reporting under the PQRS that provides measures available for reporting related to breast cancer and colon cancer. We believe it is important to measure cancer care.

We propose the following 4 measures groups for inclusion in the PQRS beginning with reporting periods occurring in 2014: Osteoporosis; Total Knee Replacement; Radiation Dose; and Preventive Cardiology. These measures groups address conditions that the measures groups established in 2012 do not address.

In 2012, the PQRS included a community-acquired pneumonia (CAP) measures group among others. We are not proposing to include this measures group again in the PQRS measure set for the 2013 PQRS or subsequent years because measures contained within this measures group were not recommended for retention by the Measure Applications Partnership. We are also proposing, as identified in Table 47, to change the composition of the Coronary Artery Disease (CAD) measures group from what was finalized for 2012. Specifically, we are proposing to remove PQRS measure #196: Coronary Artery Disease (CAD): Symptom and Activity Assessment and replace this measure with PQRS measure #242: Coronary Artery

Disease (CAD): Symptom Management in the CAD measures group, because the measure #196 was not recommended for retention by the measure applications partnership. On the hand, measure #242 was recommended for retention by the Measure Applications Partnership.

Descriptions of the measures we are proposing within each proposed measures group are provided in Tables 37 through 62. Please note that some of the proposed measures included within a proposed PQRS quality measures group may also be available for reporting as an individual measure.

**TABLE 37: 2013 and Beyond Proposed Measures – Diabetes Mellitus Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0059/ 1 | **Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0 percent | NCQA |
| 0064/ 2 | **Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** 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 |
| 0061/ 3 | **Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) | NCQA |
| 0055/ 117 | **Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient:** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dialated eye exam | NCQA |
| 0062/ 119 | **Diabetes Mellitus: Urine Screening:** Percentage of patients aged 18 through 75 years with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy | NCQA |
| 0056/ 163 | **Diabetes Mellitus: Foot Exam:** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination | NCQA |

*This measures group is reportable through both claims and registry-based reporting.

**TABLE 38: 2013 and Beyond Proposed Measures – Chronic Kidney Disease (CKD) Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0041/ 110 | **Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older who received an influenza immunization during the flu season (October 1 through March 31) | AMA-PCPI |
| AQA adopted/1 21 | **Adult Kidney Disease: Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of 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/1 22 | **Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and documented proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care | AMA-PCPI |
| AQA adopted/1 23 | **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 | AMA-PCPI |

| | | |
|---|---|---|
| | 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 ESA therapy AND have a Hemoglobin level > 12.0 g/dL | |

*This measures group is reportable through both claims and registry-based reporting

## TABLE 39: 2013 and Beyond Proposed Measures – Preventive Care Measures Group*

| 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 who received an influenza immunization during the flu season (October 1 through March 31) | AMA-PCPI |
| 0043/ 111 | **Preventive Care and Screening: Pneumonia 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: Screening Mammography:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer | 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 a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented. Normal Parameters: Age 65 years and older BMI ≥ 23and < 30; Age 18 – 64 years BMI > 18.5 and < 25. | CMS/ QIP |
| AQA adopted/173 | **Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months | AMA-PCPI |
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |

*This measures group is reportable through both claims and registry-based reporting

## TABLE 40: 2013 and Beyond Proposed Measures – Coronary Artery Bypass Graft (CABG) Measures Group*

| 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 using an IMA graft | STS |
| 0236/ 44 | **Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery 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 intubation > 24 | STS |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| | hours | |
| 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 |

*This measures group is reportable through registry-based reporting only

## TABLE 41: 2013 and Beyond Proposed Measures – Rheumatoid Arthritis (RA) Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0054/ 108 | **Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD | NCQA |
| AQA adopted/1 76 | **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/ NCQA |
| AQA adopted/1 77 | **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/ NCQA |
| 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/ NCQA |
| AQA adopted/1 79 | **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/ NCQA |
| AQA adopted/1 80 | **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 prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months | AMA-PCPI/ NCQA |

*This measures group is reportable through both claims and registry-based reporting

**TABLE 42: 2013 and Beyond Proposed Measures – Perioperative Care Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0270/ 20 | **Perioperative Care: Timing of Antibiotic Prophylaxis – 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 cefazolin OR cefuroxime for antimicrobial prophylaxis | AMA-PCPI/ NCQA |
| 0271/ 22 | **Perioperative Care: Discontinuation of Prophylactic 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 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 |

*This measures group is reportable through both claims and registry-based reporting

**TABLE 43: 2013 and Beyond Proposed Measures – Back Pain Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 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 |

*This measures group is reportable through both claims and registry-based reporting

**TABLE 44: 2013 and Beyond Proposed Measures – Hepatitis C Measures Group***

| 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 |
| 0397/ | **Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and | AMA- |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 86 | older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period | PCPI |
| 0398/ 87 | **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 | AMA-PCPI |
| 0401/ 89 | **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 | AMA-PCPI |
| 0394/ 90 | **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 | AMA-PCPI |
| 0399/ 183 | **Hepatitis C: Hepatitis A 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 A vaccine, or who have documented immunity to hepatitis A | AMA-PCPI |
| 0400/ 184 | **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 | AMA-PCPI |

*This measures group is reportable through both claims and registry-based reporting

## TABLE 45: 2013 and Beyond Proposed Measures – Heart Failure (HF) Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0081/ 5 | **Heart Failure: 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 and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy | AMA-PCPI/ ACCF/AHA |
| 0083/ 8 | **Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy | AMA-PCPI/ ACCF/AHA |
| 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 result (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 aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |

*This measures group is reportable through registry-based reporting only

## TABLE 46: 2013 and Beyond Proposed Measures – Coronary Artery Disease (CAD) Measures Group*

| 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 |
| 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 | AMA-PCPI/ ACCF/AH |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| | documented plan of care to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin | A |
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |
| N/A/ 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 and with results of an evaluation of level of activity AND an assessment for the presence *or* absence of anginal symptoms, with a plan of care to manage anginal symptoms, if present | AMA-PCPI/ ACCF/ AHA |

*This measures group is reportable through registry-based reporting only

## TABLE 47: 2013 and Beyond Proposed Measures – Ischemic Vascular Disease (IVD) Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0073/ 201 | **Ischemic Vascular Disease (IVD): Blood Pressure Management Control:** Percentage of patients aged 18 years and older with ischemic vascular disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg) | 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 other antithrombotic | NCQA |
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |
| 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 |

*This measures group is reportable through both claims and registry-based reporting

## TABLE 48: 2013 and Beyond Proposed Measures – HIV/AIDS Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 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/mm3 who were prescribed PCP prophylaxis within 3 months of low CD4+ cell count | AMA-PCPI/ NCQA |
| 0406/ 161 | **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/mm3 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 | AMA-PCPI/ NCQA |
| 0407/ 162 | **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 | AMA-PCPI/ NCQA |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| | have documentation of a plan of care | |
| 0409/ 205 | **HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia and gonorrhea screenings were performed at least once since the diagnosis of HIV infection | AMA-PCPI/ NCQA |
| 0413/ 206 | **HIV/AIDS: Screening for High Risk Sexual Behaviors:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for high risk sexual behaviors at least once within 12 months | AMA-PCPI/ NCQA |
| 0415/ 207 | **HIV/AIDS: Screening for Injection Drug Use:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for injection drug use at least once within 12 months | AMA-PCPI/ NCQA |
| 0410/ 208 | **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 | AMA-PCPI/ NCQA |

*This measures group is reportable through registry-based reporting only

## TABLE 49: 2013 and Beyond Proposed Measures – Asthma Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0047/ 53 | **Asthma: Pharmacologic Therapy for Persistent Asthma:** Percentage of patients aged 5 through 50 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment | AMA-PCPI/ NCQA |
| 0001/ 64 | **Asthma: Assessment of Asthma Control:** Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated during at least one office visit within 12 months for the frequency (numeric) of daytime and nocturnal asthma symptoms | AMA-PCPI/ NCQA |
| 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 |

*This measures group is reportable through both claims and registry-based reporting

## TABLE 50: 2013 and Beyond Proposed Measures – Chronic Obstructive Pulmonary Disease (COPD) Measures Group*

| 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): Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70 percent 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 who received an influenza immunization during the flu season (October 1 through March 31) | AMA-PCPI |
| 0043/ 111 | **Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older:** Percentage of patients aged 65 years and older who have ever received a | NCQA |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| | pneumococcal vaccine | |
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |

*This measures group is reportable through both claims and registry-based reporting

**TABLE 51: 2013 and Beyond Proposed Measures – Inflammatory Bowel Disease (IBD) Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |
| N/A/ 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 10mg/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 |

*This measures group is reportable through registry-based reporting only

**TABLE 52: 2013 and Beyond Proposed Measures – Sleep Apnea Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 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 | AMA-PCPI/ |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| | an assessment of symptoms, including presence or absence of snoring and daytime sleepiness | 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 |

*This measures group is reportable through registry-based reporting only

**TABLE 53: 2013 and Beyond Proposed Measures – Dementia Measures Group***

| 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 driving alternatives 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 |

*This measures group is reportable through claims and registry-based reporting

**TABLE 54: 2013 and Beyond Proposed Measures – Parkinson's Disease Measures Group***

| 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 than 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 |

*This measures group is reportable through registry-based reporting only

**TABLE 55: 2013 and Beyond Proposed Measures – Hypertension Measures Group***

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| N/A/ 295 | **Hypertension: Appropriate Use of Aspirin or Other Antiplatelet or Anticoagulant Therapy:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who were prescribed aspirin or other anticoagulant/antiplatelet therapy | ABIM |
| N/A/ 296 | **Hypertension: Complete Lipid Profile:** Percentage of patients aged 15 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 24 months | ABIM |
| N/A/ 297 | **Hypertension: Urine Protein Test:** Percentage of patients aged 15 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 15 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 15 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 15 through 90 years old with a diagnosis of hypertension who had most recent blood pressure level under control (at goal) | ABIM |
| N/A/ 301 | **Hypertension: Low Density Lipoprotein (LDL-C) Control:** Percentage of patients aged 15 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 15 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 | ABIM |

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| | months | |

*This measures group is reportable through registry-based reporting only

## TABLE 56: 2013 and Beyond Proposed Measures – Cardiovascular Prevention Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 0064/ 2 | **Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus:** 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 other antithrombotic | NCQA |
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |
| 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:** Percentage of patients aged 18 and older who are screened for high blood pressure | CMS/ QIP |

*This measures group is reportable through both claims and registry-based reporting

## TABLE 57: 2013 and Beyond Proposed Measures – Cataracts Measures Group*

| NQF/ PQRS | Measure Title and Description | Measure Developer |
|---|---|---|
| 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 |
| 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 |

*This measures group is reportable through registry-based reporting only

**TABLE 58: 2013 and Beyond Proposed Measures – Oncology Measures Group***

| 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 Stage III Colon Cancer Patients:** Percentage of patients aged 18 years and older with Stage IIIA through IIIC 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 who received an influenza immunization during the flu season (October 1 through March 31) | 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, vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route | CMS/ QIP |
| 0384/ 143 | **Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified | AMA-PCPI |
| 0383/ 144 | **Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of patient visits, regardless of patient 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 breast, colon, or rectal cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once within 12 months | AMA-PCPI/ ASCO |
| 0028/ 226 | **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user | AMA-PCPI |

*This measures group is reportable through registry-based reporting only

**TABLE 59: 2014 and Beyond Proposed Measures – Osteoporosis Measures Group***

| NQF/ PQRS | Measure Title | Measure Developer |
|---|---|---|

| NQF/ PQRS | Measure Title | Measure Developer |
|---|---|---|
| 0046/ 39 | **Osteoporosis: 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 |
| 0049/ 41 | **Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months | AMA |
| AQA Selected /154 | **Falls: Risk Assessment for Falls:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months | NCQA |
| AQA Selected /155 | **Falls: Plan of Care for Falls:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months | NCQA |
| N/A / TBD | **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 | ABIM |
| N/A / TBD | **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 | ABIM |
| N/A / TBD | **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 | ABIM |
| N/A / TBD | **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 | ABIM |
| N/A / TBD | **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 | ABIM |
| N/A / TBD | **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 | ABIM |
| N/A / TBD | **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 | ABIM |

*This measures group is reportable through claims and registry-based reporting

## TABLE 60: 2014 and Beyond Proposed Measures – Total Knee Replacement Measures Group*

| NQF/ PQRS | Measure Title | Measure Developer |
|---|---|---|

| NQF/ PQRS | Measure Title | Measure Developer |
|---|---|---|
| N/A / TBD | **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 | AAHKS/AMA-PCPI |
| N/A / TBD | **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 / TBD | **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 / TBD | **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 |

*This measures group is reportable through and registry-based only

## TABLE 61: 2014 and Beyond Proposed Measures – Radiation Dose Optimization Measures Group*

| NQF/ PQRS | Measure Title | Measure Developer |
|---|---|---|
| TBD/ TBD | **Radiation Dose Optimization: Utilization of a Standardized Nomenclature for 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 (e.g., RadLex®) and the standardized nomenclature is used in institutions computer systems | AMA-PCPI |
| TBD/ TBD | **Radiation Dose Optimization: Cumulative Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) Scans and Cardiac Nuclear Medicine Scans:** Percentage of CT and cardiac nuclear medicine (myocardial perfusion) imaging reports for all patients, regardless of age, that document a count of known previous CT studies (any type of CT) and cardiac nuclear medicine (myocardial perfusion studies) studies that the patient has received in the 12-month period prior to the current study | AMA-PCPI |
| TBD/ TBD | **Radiation Dose Optimization: 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 |
| TBD/ TBD | **Radiation Dose Optimization: Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for imaging studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available reciprocally to non-affiliated external entities on a secure, media free, searchable basis with patient authorization for at least a 12-month period after the study | AMA-PCPI |
| TBD/ TBD | **Radiation Dose Optimization: Search for Prior Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of imaging 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 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 |

*This measures group is reportable through both claims and registry-based reporting

**TABLE 62: 2014 and Beyond Proposed Measures – Preventive Cardiology Measures Group***

| NQF/ PQRS | Measure Title | Measure Developer |
|---|---|---|
| N/A/ TBD | **Preventive Cardiology Composite: Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal | ABIM |
| N/A/ TBD | **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 | ABIM |
| N/A/ TBD | **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) | ABIM |
| N/A/ TBD | **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 | ABIM |
| N/A/ TBD | **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 | ABIM |
| N/A/ TBD | **Preventive Cardiology Composite: Counseling for Diet and Physical Activity:** Percentage of patients in the sample who received dietary and physical activity counseling | ABIM |
| N/A/ TBD | **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% | ABIM |
| N/A/ TBD | **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 | ABIM |

*This measures group is reportable through both claims and registry-based reporting

We invite public comment on the proposed Physician Quality Reporting System measures groups.

(5) Proposed Physician Quality Reporting System Measures for Eligible Professionals and Group Practices that Report Using Administrative Claims for the 2015 and 2016 Payment Adjustments

We are proposing the following measures in Table 63 for eligible professionals and group

practices that report using administrative claims for the 2015 and 2016 payment adjustments. Our proposals on how to attribute beneficiaries to groups of physicians that elect the administrative claims option are discussed in the value-based payment modifier in section K. below. We considered all of the measures included in the program year 2010 individual Physician Feedback reports that can be calculated using administrative claims but are proposing only a subset of the measures that were included in the program year 2010 individual Physician Feedback reports. We are proposing this subset of measures for both the PQRS payment adjustment and the value-based modifier because we believe these measures are clinically meaningful, focus on highly prevalent conditions among beneficiaries, have the potential to differentiate physicians, and be statistically reliable. To the extent that the value-based payment modifier finalizes other measures from the 2010 individual Physician Feedback reports that are listed in Table 65, it would be our intent to finalize those additional measures as well for purposes of the 2015 and 2016 PQRS payment adjustments so that the two programs can be aligned.

As specified in Table 63, we are proposing 19 measures. Of these 19 proposed measures, 17 of these measures are NQF-endorsed and therefore satisfying section 1848(k)(2)(C)(i) if the Act. With respect to the 2 measures that are not NQF-endorsed, "Potentially Harmful Drug-Disease Interactions in the Elderly" and "Diabetes: LDL-C Screening ," we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose these measures for inclusion in the PQRS administrative claims measure set. Both of these measures are relevant as they address care coordination by measuring the amount of time a patient has been readmitted and/or where their status is in the healthcare continuum following hospitalization. The utilization of the administrative claims measures will allow PQRS to implement different reporting options

which capture a wider venue of participants without using the traditional methods of reporting and eliminate the potential payment adjustment for non-participators.

**TABLE 63: Proposed Measures for Eligible Professionals and Group Practices Who Report Using Administrative Claims for the 2015 and 2016 PQRS Payment Adjustment**

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| 0279 | **Bacterial Pneumonia**<br>The number of admissions for bacterial pneumonia per 100,000 population. | AHRQ | Care Coordination |
| 0281 | **UTI**<br>The number of discharges for urinary tract infection per 100,000 population Age 18 Years and Older in a one year time period | AHRQ | Care Coordination |
| 0280 | **Dehydration**<br>The number of admissions for dehydration per 100,000 population. | AHRQ | Care Coordination |
| | **Composite of Chronic Prevention Quality Indicators** | N/A | |
| | **Diabetes Composite** | | |
| 0638 | **Uncontrolled diabetes**<br>The number of discharges for uncontrolled diabetes per 100,000 population Age 18 Years and Older in a one year time period. | AHRQ | Care Coordination |
| 0272 | **Short Term Diabetes complications**<br>The number of discharges for diabetes short-term complications per 100,000 Age 18 Years and Older population in a one year period. | AHRQ | Care Coordination |
| 0274 | **Long term diabetes complications**<br>The number of discharges for long-term diabetes complications per 100,000 population Age 18 Years and in a one year time period. | AHRQ | Care Coordination |
| 0285 | **Lower extremity amputation for diabetes**<br>The number of discharges for lower-extremity amputation among patients with diabetes per 100,000 population Age 18 Years in a one year time period. | AHRQ | Care Coordination |
| 0275 | **COPD**<br>The number of admissions for chronic obstructive pulmonary disease (COPD) per 100,000 population. | AHRQ | Care Coordination |
| 0277 | **Heart Failure**<br>Percent of the population with admissions for CHF. | AHRQ | Care Coordination |
| N/A | **All Cause Readmission**<br>The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned. | CMS | Care Coordination |
| N/A | **30 Day Post Discharge Visit**<br>The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned. | CMS | Care Coordination |
| 0576 | **Follow-Up After Hospitalization for Mental Illness**<br>Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner | NCQA | Care Coordination |
| 0021 | **Annual Monitoring for Beneficiaries on Persistent Medications**<br>Percentage of patients 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. | NCQA | Patient Safety |
| 0555 | **Lack of Monthly INR Monitoring for Beneficiaries on Warfarin**<br>Average percentage of 40-day intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period. | CMS | Patient Safety |
| 0577 | **Use of Spirometry Testing to Diagnose COPD**<br>Percentage of patients at least 40 years old who have a new diagnosis or newly active chronic obstructive pulmonary disease (COPD) who received appropriate spirometry testing to confirm the diagnosis. | NCQA | Clinical Care |
| 0549 | **Pharmacotherapy Management of COPD Exacerbation**<br>Percentage of chronic obstructive pulmonary disease (COPD) exacerbations for patients 40 | NCQA | Clinical Care |

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| | years of age and older who had an acute inpatient discharge or ED encounter between January 1–November 30 of the measurement year and were dispensed appropriate medications | | |
| 0543 | **Statin Therapy for Beneficiaries with Coronary Artery Disease** Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease. | CMS | Clinical Care |
| 0583 | **Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications** Percentage of patients age 18 or older starting lipid-lowering medication during the measurement year who had a lipid panel checked within 3 months after starting drug therapy | Resolution Health | Clinical Care |
| 0053 | **Osteoporosis Management in Women ≥ 67 Who Had a Fracture** Percentage of women 67 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six months after the date of fracture. | NCQA | Clinical Care |
| 0055 | **Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 years who received a dilated eye exam by an ophthalmologist or optometrist during the measurement year, or had a negative retinal exam (no evidence of retinopathy) by an eye care professional in the year prior to themeasurement year. | NCQA | Clinical Care |
| 0057 | **HbA1c Testing for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 years receiving one or more A1c test(s) per year. | NCQA | Clinical Care |
| 0062 | **Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes** Percentage of adult diabetes patients aged 18-75 years with at least one test nephropathy screening test during the measurement year or who had evidence existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria). | NCQA | Clinical Care |
| 0063 | **Lipid Profile for Beneficiaries ≤ 75 with Diabetes** Percentage of adult patients with diabetes aged 18-75 who had an LDL-C test performed during the measurement year. | NCQA | Clinical Care |
| 0075 | **Lipid Profile for Beneficiaries with Ischemic Vascular Disease** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to measurement year, who had a complete lipid profile during the measurement year. | NCQA | Clinical Care |
| 0105 | **Antidepressant Treatment for Depression** Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner. | NCQA | Clinical Care |
| 0031 | **Breast Cancer Screening for Women ≤ 69** Percentage of eligible women 40-69 who receive a mammogram in during the measurement year or in the year prior to the measurement year. | NCQA | Clinical Care |

We invite public comment on the proposed measures for eligible professionals and group practices that report using administrative claims. We seek comment on whether these are these proposed measures.

7. Proposed Maintenance of Certification Program Incentive: Proposed Self-Nomination Process for Entities Wishing to be Qualified for the 2013 and 2014 Maintenance of Certification Program Incentives

We propose that new and previously qualified entities wishing to become qualified to

provide their members with an opportunity to earn the 2013 and/or 2014 Maintenance of Certification Program incentives undergo a self-nomination and qualification process. Once qualified, the entity would be able to submit data on behalf of its eligible professionals.

For the self-nomination process, we propose that an entity wishing to be qualified for the 2013 and/or 2014 Maintenance of Certification Program incentive would be required to submit a self-nomination statement containing all of the following information via the web:

- Provide detailed information regarding the Maintenance of Certification Program with reference to the statutory requirements for such program.
- Indicate the organization sponsoring the Maintenance of Certification Program, and whether the Maintenance of Certification Program is sponsored by an American Board of Medical Specialties (ABMS) board. If not an ABMS board, indicate whether and how the program is substantially equivalent to the ABMS Maintenance of Certification Program process.
- Indicate that the program is in existence as of January 1 the year prior to the year in which the entity seeks to be qualified for the Maintenance of Certification Program incentive. For example, to be qualified for the 2013 Maintenance of Certification Program incentive, the entity would be required to be in existence by January 1, 2012.
- Indicate that the program has at least one (1) active participant.
- The frequency of a cycle of Maintenance of Certification for the specific Maintenance of Certification Program of the sponsoring organization, including what constitutes "more frequently" for both the Maintenance of Certification Program itself and the practice assessment for the specific Maintenance of Certification Program of the sponsoring organization.
- Confirmation from the board that the practice assessment will occur and be completed in the year the physician is participating in the Maintenance of Certification Program Incentive.
- What was, is, or will be the first year of availability of the Maintenance of

Certification Program practice assessment for completion by an eligible professional.

- What data is collected under the patient experience of care survey and how this information would be provided to CMS.
- Describe how the Maintenance of Certification program monitors that an eligible professional has implemented a quality improvement process for their practice.
- Describe the methods, and data used under the Maintenance of Certification Program, and provide a list of all measures used in the Maintenance of Certification Program for the year prior to which the entity seeks to be qualified for the Maintenance of Certification Program incentive (for example, measures used in 2012 for the 2013 Maintenance of Certification Program incentive), including the title and descriptions of each measure, the owner of the measure, whether the measure is NQF endorsed, and a link to a website containing the detailed specifications of the measures, or an electronic file containing the detailed specifications of the measures.

For the qualification process, we propose that an entity must meet all of the following requirements to be considered for qualification for purposes of the 2013 and 2014 Maintenance of Certification Program incentives:

- The name, NPI and applicable TINs of eligible professionals who would like to participate for the 2013 and/or 2014 Maintenance of Certification Program incentives.
- Attestation from the board that the information provided to CMS is accurate and complete.
- The board has signed documentation from eligible professional(s) that the eligible professional wishes to have the information released to us.
- Information from the patient experience of care survey.
- Information certifying the eligible professional has participated in a Maintenance of

Certification Program for a year, "more frequently" than is required to qualify for or maintain board certification status, including the year the physician met the board certification requirements for the Maintenance of Certification Program, and the year the eligible professional participated in the Maintenance of Certification Program "more frequently" than is required to maintain or qualify for board certification.

- Information certifying the eligible professional has completed the Maintenance of Certification Program practice assessment at least one time each year the eligible professional participates in the Maintenance of Certification Program Incentive.

We are proposing this self-nomination and qualification process because the process is identical to the self-nomination and qualification process finalized for the 2011 and 2012 Maintenance of Certification Program incentives and we believe such requirements remain appropriate. As the incentives only run through 2014, we believe it is important to keep the requirements consistent with what has been required for the 2011 and 2012 Maintenance of Certification Program incentives. We invite public comment on our proposed self-nomination and qualification process for entities who wish to be qualified for the 2013 and 2014 Maintenance of Certification Program incentive.

8. Informal Review

We established an informal review process for 2012 and beyond in the CY 2012 Medicare PFS final rule (76 FR 73390). In this proposed rule, we address the additional parameters of eligible professionals and group practices subject to a PQRS payment adjustment requesting an informal review. For eligible professionals and group practices that are subject to the payment adjustments that wish to request an informal review, in addition to the requirements we previously established, we propose the following:

- For eligible professionals and group practices wishing to submit an informal review

related to the payment adjustment, we propose that an eligible professional electing to utilize the informal review process must request an informal review by February 28 of the year in which the payment adjustment is being applied. For example, if an eligible professional requests an informal review related to the 2015 payment adjustment, the eligible professional would be required to submit his/her request for an informal review by February 28, 2015. We believe this deadline provides ample time for eligible professionals and group practices to discover that their respective claims are being adjusted due to the payment adjustment.

- Where we find that the eligible professional or group practice did satisfactorily report for the payment adjustment, we propose to cease application of the payment adjustment and reprocess all claims that have been erroneously adjusted to date.

We invite public comment on our proposals for the PQRS informal review process.

H. The Electronic Prescribing (eRx) Incentive Program

We established the requirements for the 2013 and 2014 eRx Incentive Program in the CY 2012 Medicare PFS final rule (76 FR 73393). This section contains additional proposals for the 2013 and 2014 eRx Incentive Program.

1. Proposed Alternative Self-Nomination Process for Certain Group Practices Under the eRx GPRO

In the CY 2012 Medicare PFS final rule (76 FR 73394), we established that a group practice wishing to participate in the eRx Incentive Program under the eRx GPRO must self-nominate via the web. However, we propose an alternative submission mechanism for self-nomination by groups participating in the MSSP, Pioneer ACO, or PGP Demonstration. Specifically, we propose that the participating TINs within these groups that wish to participate in the eRx Incentive Program using the eRx GPRO must submit a self-nomination statement by sending a letter indicating its intent to participate in the eRx Incentive Program under the eRx

GPRO. We also propose that the group practice must submit an XML file describing the eligible professionals included in the group practice. We are proposing this alternative submission mechanism for group practices that are participating as groups in the MSSP, Pioneer ACO, or PGP Demonstration because it is not technically feasible for CMS to receive this information from these group practices via the web. We invite public comment on this proposed alternative mechanism for submitting self-nomination statements and the XML file for the types of group practices identified above that want to participate in the eRx Incentive Program using the eRx GPRO.

2. The 2013 Incentive: Proposed Criterion for Being a Successful Electronic Prescriber for Groups Comprised of 2-24 Eligible Professionals Selected to Participate under the eRx GPRO

As stated in section III.G, we are proposing to modify §414.90(b) to define a group practice as "a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN." Under §414.92(b), we define a group practice as a practice that indicates its desire to participate in the eRx group practice option and meets the definition of group practice according to the PQRS at §414.90(b), or a group practice participating in certain other Medicare programs (for example, PGP demonstration, Shared Savings Program). Therefore, since we are proposing to change the minimum group practice size from 25 to 2, we are proposing to add another criterion for being a successful electronic reporter under the program for the 2013 Incentive (for the other criteria we previously adopted for the ERx GPRO Reporting Option, please see 76 FR 73407). Specifically, we are proposing the following criterion for being a successful electronic prescriber for group practices participating in the eRx GPRO comprised of 2-24 eligible professionals for purposes of the 2013 eRx incentive: report the electronic prescribing measure's numerator code during a denominator-eligible encounter for

at least 225 times during the 12-month 2013 incentive reporting period (January 1, 2013—December 31, 2013). We are proposing lower criterion for group practices participating under the eRx GPRO with 2-24 eligible professionals because we understand that their smaller sizes necessitate a lower reporting threshold. We chose this reporting threshold because this reporting threshold is familiar to group practices, as this was the threshold established for group practices comprised of 11-25 eligible professionals that participated in the GPRO II in 2010 (75 FR 73509). We invite public comment on our proposed criterion for being a successful electronic prescriber for the 2013 incentive for groups comprised of 2-24 eligible professionals.

3. The 2014 Payment Adjustment: Proposed Criterion for Being a Successful Electronic Prescriber for Groups Comprised of 2-24 Eligible Professionals Selected to Participate under the eRx GPRO

As stated in section III.G, we are proposing to modify §414.90(b) to define a group practice as "a single Tax Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider (NPI), who have reassigned their Medicare billing rights to the TIN." Under §414.92(b), we define a group practice for the purposes of being able to participate under the eRx GPRO as a practice that indicates its desire to participate in the eRx group practice option and either meets the definition of group practice according to the PQRS at §414.90(b) or is a group practice participating in certain other Medicare programs (for example, PGP demonstration, Shared Savings Program). Therefore, since we are proposing to change the minimum group practice size from 25 to 2, we are proposing to add another criterion for being a successful electronic reporter under the program for the 2014 payment adjustment (for the other criteria we previously adopted for the ERx GPRO Reporting Option, please see 76 FR 73412-73414). Specifically, we are proposing the following criterion for being a successful electronic prescriber for purposes of the 2014 payment adjustment for group practices comprised of 2-24

eligible professionals participating under the eRx GPRO: Report the electronic prescribing measure's numerator code at least 225 times for the 6-month 2014 payment adjustment reporting period (January 1, 2013—June 30, 2013). We are proposing this lower criterion for group practices participating under the eRx GPRO with 2-24 eligible professionals because we understand that their smaller sizes necessitate a lower reporting threshold. In addition, we note that this reporting threshold is familiar to group practices, as this was the threshold established for group practices comprised of 11-25 eligible professionals that participated in the GPRO II in 2010 (75 FR 73509). We invite public comment on the proposed criterion for being a successful electronic prescriber for the 2014 eRx payment adjustment for the 6-month payment adjustment reporting period for group practices composed of 2-24 eligible professionals.

4. Proposed Analysis for the Claims-based Reporting Mechanism

We understand that, in certain instances, it is permissible for an eligible professional to have their Medicare Part B claims reprocessed. Please note that, if a Medicare Part B claim is reopened for reprocessing, the reprocessing of claim does not allow an eligible professional to attach a G-code on a claim for purposes of reporting quality measures, such as the electronic prescribing measure. Therefore, we are proposing to modify §414.92 to indicate that claims may not be reprocessed for the sole purpose of attaching a reporting G-code on a claim.

5. Proposed Significant Hardship Exemptions

Section 1848(a)(5)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment, if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. In the CY 2012 final rule with comment period, we finalized, as set forth at §414.92(c)(2)(ii)(B), four circumstances under which an eligible professional or eRx GPRO can request consideration for a significant

hardship exemption for the 2013 and 2014 eRx payment adjustments (76 FR 73413):

- The eligible professional or group practice practices in a rural area with limited high speed internet access.
- The eligible professional or group practice practices in an area with limited available pharmacies for electronic prescribing.
- The eligible professional or group practice is unable to electronically prescribe due to local, state, or Federal law or regulation.
- The eligible professional or group practice has limited prescribing activity, as defined by an eligible professional generating fewer than 100 prescriptions during a 6-month reporting period.

We have received feedback from stakeholders requesting significant hardship exemptions from application of the eRx payment adjustment based on participation in the EHR Incentive Program, a program which requires a certain level of electronic prescribing activity. Under the EHR Incentive Program, eligible professionals[4] may receive incentive payments beginning in CY 2011 for successfully demonstrating "meaningful use" of Certified EHR Technology (CEHRT) and will be subject to payment adjustments beginning in CY 2015 for failure to demonstrate meaningful use. For further explanation of the statutory authority and regulations for the EHR Incentive Program, we refer readers to the July 28, 2010 final rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule," (75 FR 44314). As a result of such feedback, we believe that in certain circumstances it may be a significant hardship for eligible professionals and group practices who are participants of the EHR Incentive Program to comply with the successful electronic prescriber requirements of the eRx Incentive Program. Therefore, we are proposing to revise the regulation at

[4] "Eligible professional" is defined for the EHR Incentive Program at 42 C.F.R. §§ 495.4, 495.100, and 495.304.

§414.92(c)(2)(ii)(B) to add the following two additional significant hardship exemption categories for the 2013 and 2014 eRx payment adjustments:

- Eligible professionals or group practices who achieve meaningful use during certain eRx payment adjustment reporting periods.
- Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology.

A. Eligible professionals or group practices who achieve meaningful use during certain 2013 and 2014 eRx payment adjustment reporting periods.

Under Stage 1 of meaningful use for the EHR Incentive Program, an eligible professional is required to meet certain objectives and associated measures in order to achieve meaningful use. One of these objectives is for the eligible professional to generate and transmit permissible prescriptions electronically, and the measure of whether the eligible professional has met this objective is more than 40 percent of all permissible prescriptions written by the eligible professional are transmitted electronically using Certified EHR Technology (§495.6(d)(4)). We note that the EHR Incentive Program and the eRx Incentive Program share a common goal of encouraging electronic prescribing and the adoption of technology that enables eligible professionals to electronically prescribe. This goal is advanced under each program via the respective program requirements – the electronic prescribing objective under the EHR Incentive Program and the requirement that an EP be a "successful electronic prescriber" under the eRx Incentive Program. Indeed, both programs require that the eligible professionals indicate their electronic prescribing activity. Under the EHR Incentive Program, an eligible professional must attest to the percentage of his or her permissible prescriptions that were generated and transmitted electronically using Certified EHR Technology during the applicable EHR reporting period, which must exceed 40 percent. Under the eRx Incentive Program, to avoid the payment

adjustment, eligible professional must be a successful electronic prescriber, which is achieved by the reporting of the eRx quality measure a certain number of instances during the applicable reporting period (each instance of reporting of the eRx quality, which includes reporting of specific quality data codes, signifies that the professional generated an electronic prescription for a specified service or encounter). In most cases, we believe the electronic prescribing objective of meaningful use would be a more rigorous standard for eligible professionals to meet than the standard adopted under the eRx Incentive Program (as demonstrated via the reporting of the eRx quality measure). In addition, there seems to be no added benefit with regard to reporting (presumably lower) electronic prescribing activity under the eRx Incentive Program given that the identical goals (encouraging electronic prescribing) of both programs would have been fulfilled through the eligible professional's achievement of meaningful use. For those reasons, we believe it may pose a significant hardship for eligible professionals who are meaningful EHR users to additionally comply with the requirements of being a successful electronic prescriber under the eRx Incentive program.

For the reasons stated, under this proposed significant hardship category, we propose that individual eligible professionals (and every eligible professional member of a group practice group practice practices for the 2014 payment adjustment only) would need to achieve meaningful use of Certified EHR Technology for a continuous 90-day EHR reporting period (as defined for the EHR Incentive Program) that falls within the 6-month reporting period (January 1 - June 30, 2012) for the 2013 eRx payment adjustment or the 12- or 6-month reporting periods (January 1-December 31, 2012 or January1 – June 30, 2013, respectively) for the 2014 eRx payment adjustment to be eligible to request a significant hardship exemption. We also propose that for purposes of the 2013 and 2014 eRx payment adjustments this hardship exemption category would apply to individual EPs and group practices (that is, every member of the group) who

instead achieve meaningful use of Certified EHR Technology for an EHR reporting period that is the full CY 2012. In section III.H.5.b. below, we discuss the proposed deadlines and procedures for requesting consideration of an exemption under this proposed significant hardship exemption category.

B. Eligible professionals or group practices who demonstrate intent to participate in the EHR Incentive Program and adoption of Certified EHR Technology

We note that we finalized at §414.92(c)(2)(ii)(A)(3) a significant hardship exemption category for the 2012 eRx payment adjustment, under which eligible professionals and group practices seeking consideration for an exemption were required to register to participate in the EHR Incentive Program and adopt CEHRT (76 FR 54958). That significant hardship category addressed significant hardships relating to the selection, purchase and adoption of eRx technology (for example, potential significant financial hardship of purchasing two sets of eRx equipment for both programs) that may have occurred as a result of the timing of the release of the standards and requirements for CEHRT and the Certified Health IT Product List, the establishment of the respective program requirements for the eRx and EHR Incentive Programs, and the 2012 eRx payment adjustment reporting periods. Given that eligible professionals have had adequate time to identify EHR products that have been certified and that the requirements for these programs have been implemented and, various stages of reporting are underway, we do not believe this significant hardship exemption category would continue to be applicable for the 2013 and 2014 eRx payment adjustments. We understand, however, that although an eligible professional may now have the requisite information about requirements for CEHRT and each respective program, there may nevertheless exist a significant hardship with regard to compliance with the requirements for being a successful electronic prescriber under the eRx

Incentive Program, given the nature of CEHRT and how it is used/implemented in one's practice.

When an eligible professional or eligible professional in a group practice first adopts CEHRT, we understand significant changes may be required with regard to how the eligible professional's practice operates. Further, necessary steps are involved in fully implementing CEHRT once it has been adopted, including: installation, configuration, customization, training, workflow redesign and the establishment of connectivity with entities that facilitate electronic health information exchange (such as for electronic prescriptions). Thus, we believe it would be difficult for an eligible professional or eligible professional in a group practice who has adopted CEHRT to be able to begin electronically prescribing on day one. Rather, we expect a natural lag time would likely occur between an eligible professional's adoption of CEHRT and the point at which CEHRT has been fully implemented such that an eligible professional could begin electronically prescribing. We believe this implementation timeline may pose a significant hardship for an eligible professional or group practice who seeks to comply with the requirements for being a successful electronic prescriber under the eRx Incentive Program and also participate for the first time in the EHR Incentive Program. Under the EHR Incentive Program, an eligible professional who is demonstrating meaningful use of CEHRT for the first time must do so for any continuous 90-day period within the calendar year (the "EHR reporting period"). In the absence of this significant hardship exemption category, eligible professionals or group practices who choose a 90-day EHR reporting period that falls later in the year may potentially have to adopt two systems (for example, a stand-alone electronic prescribing system for purposes of participating in the eRx Incentive Program, and CEHRT for purposes of participating in the EHR Incentive Program), which could be financially burdensome. Alternatively, such eligible professionals who wish to use CEHRT for purposes of participating

in both programs may potentially have to adopt and implement CEHRT well in advance of their 90-day EHR reporting period in order to meet an earlier reporting period for the eRx Incentive Program.

Therefore, for the 2013 and 2014 eRx payment adjustments, we are proposing a significant hardship exemption category to address this situation. We believe, however, that for this category it is necessary for eligible professionals and group practices to show they intend to participate in the EHR Incentive Program for the first time and have adopted CEHRT. Therefore, to be eligible for consideration for an exemption under this proposed significant hardship exemption category for the 2013 and 2014 eRx payment adjustments, we propose that eligible professionals or group practices must register to participate in the Medicare or Medicaid EHR Incentive Programs and adopt CEHRT by a date specified by CMS. We further note that, given the nature of the significant hardship at issue under this category, this proposal would be limited to eligible professionals and group practices (that is, every individual EP member of the group practice): (1) who have not previously adopted CEHRT or received an incentive payment under the Medicare or Medicaid EHR Incentive Programs; and (2) who attempt to participate in the Medicare or Medicaid EHR Incentive Programs from January 2, 2012 through October 15, 2012, or the effective date of the final rule (which includes the 6-month 2013 eRx payment adjustment reporting period of January 1, 2012-June 30, 2012) for the 2013 eRx payment adjustment, or during the 6 month payment adjustment reporting period for the 2014 eRx payment adjustment (January 1, 2013 through June 30, 2013).

With respect to eligible professionals or group practiceswho intend to adopt EHR technology in the future or have not yet taken the steps required in order to apply for this significant hardship exemption, we believe that mere intent to adopt CEHRT or attest at a later date does not sufficiently demonstrate that an eligible professional will adopt CEHRT to

participate in the Medicare or Medicaid EHR Incentive Programs. Unlike those eligible professionals who would have registered for the Medicare or Medicaid EHR Incentive Programs and have adopted CEHRT available for immediate use, we would have to monitor and provide oversight over those eligible professionals who have not yet taken these steps to participate in the Medicare or Medicaid EHR Incentive Programs. We also do not believe that such eligible professionals or group practices would necessarily be facing a significant hardship as contemplated in this proposed exemption category. Accordingly, all of the proposed requirements to qualify for an exemption under this significant hardship exemption category would need to be met by the time the eligible professional requests an exemption. In section III.H.5.b. below, we discuss the proposed deadlines and procedures for requesting consideration of an exemption under this proposed significant hardship exemption category. We invite public comment on these two proposed significant hardship exemption categories for the 2013 and 2014 payment adjustments.

C. Proposed Deadlines and Procedures for Requesting Significant Hardship Exemptions

In the CY 2012 final rule with comment period, we established a process whereby eligible professionals would submit significant hardship exemptions for the existing significant hardship exemption categories for the eRx payment adjustments (76 FR 54963). Unfortunately, with respect to submitting these proposed significant hardship exemptions for the 2013 eRx payment adjustment, it would not be operationally feasible to accept significant hardship exemption requests in the manner we previously established. Therefore, we propose that, in order to request a significant hardship under the two proposed significant hardship exemption categories for the 2013 eRx payment adjustment, CMS would analyze the information provided to us in the Registration and Attestation System under the EHR Incentive Program to determine whether the eligible professional or group practice (that is, every EP member of the group

practice) has either (1) achieved meaningful use under the EHR Incentive Program during the applicable reporting periods we noted previously, or (2) registered to participate in the EHR Incentive Program via the Registration and Attestation system for the EHR Incentive Program (located at https://ehrincentives.cms.gov/hitech/login.action) and adopted CEHRT, or both, if applicable. We understand that providing an eligible professionals CEHRT product number is an optional field in the Registration Page. Please note that if requesting a significant hardship exemption under proposed category 2, the eligible professional must provide its CEHRT product number when registering for the EHR Incentive Program. In the event that it is not operationally feasible to accept this information via the Registration and Attestation system for the EHR Incentive Program, we propose that we would accept requests for significant hardship exemptions under these two proposed categories via a mailed letter to CMS to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-1850.

Regardless of which method is finalized for the 2013 eRx payment adjustment, we propose that eligible professionals would be required to submit this significant hardship requests by October 15, 2012 or the effective date of the final rule for this provision, whichever is later. For those eligible professionals who request a significant hardship exemption based on achieving meaningful use under the EHR Incentive Program during the 12- or 6-month reporting periods for the 2013 payment adjustment, we also propose that the eligible professional would be required to have attested under the EHR Incentive Program by October 15th of 2012 (or if later, the effective date of the final rule), in order to qualify for a significant hardship exemption for the 2013 payment adjustment. For those eligible professionals requesting a significant hardship exemption for the 2013 eRx payment adjustment under the second proposed significant hardship

exemption category (that is, intent to participate in the EHR Incentive Program and adoption of CEHRT), we propose that these eligible professionals who intend to participate in the EHR Incentive Program from January 1, 2011 through October 15, 2012 or the effective date of the final rule would be required to register for the EHR Incentive Program and adopt CEHRT by the same deadline noted above, in order to qualify for a significant hardship exemption for the 2013 eRx payment adjustment.

We note that we are proposing a later deadline of October 15, 2012 (or the effective date of the final rule, if later) for the submission of these requests because the deadline for submitting requests under other previously established significant hardship exemption categories to the 2013 eRx payment adjustment (June 30, 2012) has passed and other similar dates we might choose would likely have passed by the time the final rule is effective. We note that this October 15, 2012 deadline is consistent with our intent to finalize our proposals related to these two additional significant hardship exemptions in early Fall 2012, prior to the publication of the CY 2013 Medicare PFS final rule. However, to the extent we are not able to finalize these proposals in the Fall 2012, please note that we may finalize the provisions related to the two proposed significant hardship exemption categories in the CY 2013 Medicare PFS final rule. If such is the case, we propose to extend the October 15, 2012 deadline to the effective date of the CY 2013 Medicare PFS final rule.

In addition, we would like to be able to process all such requests before we begin making the claims processing systems changes later this year to adjust eligible professionals' or group practices' payments starting on January 1, 2013. However, we anticipate that, in some cases, particularly in instances where eligible professionals submit significant hardship exemption requests closer towards the deadline, we may not be able to complete our review of the requests before the claims processing systems updates are made to begin reducing eligible professionals'

and group practices' PFS amounts in 2013. In such cases, if we ultimately approve the eligible professional or group practice's request for a significant hardship exemption after January 1, 2013, we would need to reprocess all claims for services furnished up to that point in 2013 that were paid at the reduced PFS amount, which we anticipate may take several months. In order to avoid the reprocessing of claims, we encourage eligible professionals who would be submitting a significant hardship exemption request under these two categories to do so as soon as possible, rather than waiting until the deadline to submit such a request.

We note that we are only proposing submission of requests for significant hardship exemptions under these 2 categories under an individual eligible professional level only because it is not technically feasible for us to operationally analyze information on the EHR Incentive Program's Registration and Attestation page using the TIN, as the information stored in this system is stored by NPI. However, we seek not to preclude eligible professionals currently in an eRx GPRO for 2012 from submitting requests for significant hardship exemptions under these 2 proposed categories. Therefore, to allow the submission of significant hardship requests for the 2013 eRx payment adjustment under these 2 proposed categories, we propose that eligible professionals within an eRx GPRO may, as individuals, request a significant hardship exemption under these 2 proposed categories. Please note, however, that if an entire eRx GPRO wishes to request a significant hardship exemption under these 2 proposed categories, then each eligible professional in the group practice must submit a request.

With respect to submitting exemption requests for the 2 proposed significant hardship exemption categories for the 2014 eRx payment adjustment, we propose the following method for submitting a request for a significant hardship exemption: Via the Communication Support Page (which is the method established for submitting the established significant hardship exemption categories).

In addition, we considered accepting significant hardship exemption requests for the 2 proposed significant hardship exemption categories for the 2014 eRx payment adjustment by CMS receiving eligible professional's information through the Registration and Attestation System for the EHR Incentive Program (similar to our proposed submission process for the 2013 eRx payment adjustment) and via a mailed letter to CMS using the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-1850. We invite public comment on these considered submission options.

We propose that the deadline for submitting these significant hardship exemption requests for the 2014 eRx payment adjustment would be June 30, 2013, which is the same deadline established for submitting a significant hardship exemption request for the existing significant hardship exemption categories. Additionally, and consistent with our proposal for the 2013 eRx payment adjustment, we propose that an eligible professional or group practice (that is, all members of the practice) that achieves meaningful use under the EHR Incentive Program during the 6- or 12-month reporting periods for the 2014 eRx payment adjustment would be required to attest by June 30, 2013. Similarly, for eligible professionals requesting a significant hardship exemption for the 2014 eRx payment adjustment under the second proposed significant hardship exemption category (i.e., intent to participate in the EHR Incentive Program and adoption of CEHRT), we propose that these eligible professionals who intend to participate in the EHR Incentive Program during the last six months of 2013 would be required to register for the EHR Incentive Program and adopt CEHRT by June 30, 2013, in order to qualify for a significant hardship exemption for the 2014 eRx payment adjustment. We understand that these deadlines may exclude some eligible professionals who attest or register for the EHR Incentive Program at later dates, but these deadlines are necessary in order to avoid the reprocessing of

claims. We note, however, that these proposed deadlines would not extend any deadlines applicable under the EHR Incentive Program. That is, for purposes of the EHR Incentive Program, an eligible professional must still attest to being a meaningful user by the deadline established under the EHR Incentive Program, even if such deadline falls prior to the proposed eRx Incentive program significant hardship exemption deadline. We invite public comment on this proposed process for submitting requests significant hardship exemptions under these two proposed categories.

6. Informal Review

To better facilitate issues surrounding the issuance of incentives and payment adjustments, we propose to establish an informal review process for the eRx Incentive Program. We are proposing an informal review process similar to the informal review process established for the PQRS (76 FR 73390), because eligible professionals and group practices are already familiar with this process. The proposed informal review process, which is described below, would only be available for the 2013 eRx incentive payments and the 2014 eRx payment adjustment.

For an informal review regarding the 2013 incentive, we propose that an eligible professional or group practice must request an informal review within 90 days of the release of his or her feedback report, irrespective of when an eligible professional or group practice actually accesses his/her feedback report.

For an informal review regarding the 2014 payment adjustment, we propose that an eligible professional or group practice must request an informal review by January 31, 2013. We believe this deadline provides ample time for eligible professionals and group practices to discover that their respective claims are being adjusted due to the 2014 payment adjustment and seek informal review.

We propose that the request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review. In its request for an informal review, eligible professional may also submit other information to assist in the review.

We propose that an eligible professional may request an informal review through the web. We believe use of the web would provide a more efficient way for CMS to record informal review requests, as the web would guide the eligible professional through the creation of an informal review requests. For example, the web-based tool would prompt an eligible professional of any necessary information he or she must provide. Should it be technically not feasible to receive requests for informal reviews via the web, we propose that as eligible professional would be able to request an informal review via email.

We further propose that we would make our determination and provide the eligible professional or group practice with a written response to his or her request for an informal review within 90 days of receiving the request.

Based on our informal review and once we have made a determination, we propose that we would provide the eligible professional or group practice a written response. Where we find that the eligible professional or group practice did successfully report for the 2013 incentive, we would provide the eligible professional or group practice with the applicable incentive payment. Where we find that the eligible professional or group practice did successfully report (that is, meet criteria for being a successful electronic prescriber) for purposes of the 2014 payment adjustment, we would cease application of the 2014 payment adjustment and reprocess all claims that have been adjusted.We further propose that decisions based on the informal review would be final, and there would be no further review or appeal.

We invite public comment on our proposals for the eRx Incentive Program informal review process for the 2013 incentive and the 2014 payment adjustment.

a. Proposed Criteria for the PQRS-Medicare EHR Incentive Pilot

The Medicare EHR Incentive Program provides incentive payments to eligible professionals (EPs) who demonstrate meaningful use of certified EHR technology (CEHRT). EPs who fail to demonstrate meaningful use will be subject to payment adjustments beginning in 2015. We established a phased approach to meaningful use, which we expect will include three stages (75 FR 44321), and all EPs are currently in Stage 1. In the CY 2012 Medicare PFS final rule, we established the PQRS-Medicare EHR Incentive Pilot in an effort to pilot the electronic submission of CQMs for the Medicare EHR Incentive Program and move towards the alignment of quality reporting requirements between Stage 1 of the Medicare EHR Incentive Program and the PQRS (76 FR 73422). We refer readers to the final rule for further explanation of the requirements of the Pilot (76 FR 73422 – 73425). Specifically, we established that an EP participating in the PQRS-Medicare EHR Incentive Pilot would be able to report clinical quality measures (CQMs) data extracted from Certified EHR Technology via use of a PQRS qualified direct EHR product or PQRS qualified EHR data submission vendor product (76 FR 73422). We propose to modify §495.8 to extend this Pilot for the 2013 payment year as it was finalized for the 2012 payment year. We are also proposing to remove from §495.8(a)(2)(v) the cross-reference to §495.6(d)(10) in order to conform with the proposed changes to §495.6(d) that were included in the EHR Incentive Program – Stage 2 NPRM (77 FR 13698, 13702). This proposal includes the following:

- For the 2013 payment year only, EPs intending to participate in the PQRS-Medicare EHR Incentive Pilot may use a PQRS qualified EHR data submission vendor product that would submit CQM data extracted from the EP's CEHRT to CMS. Under this option, identical to the submission process used for the Pilot in 2012 for the 2012 payment year, the PQRS qualified EHR data submission vendor would calculate the CQMs from the EP's CEHRT and then submit

the calculated results to CMS on the EP's behalf via a secure portal for purposes of this Pilot.

- For the 2013 payment year only, identical to the submission process used for the Pilot in 2012 for the 2012 payment year, EPs intending to participate in the PQRS-Medicare EHR Incentive Pilot may use a PQRS qualified direct EHR product to submit CQM data directly from his or her CEHRT to CMS via a secure portal using the infrastructure of the PQRS EHR-based reporting mechanism.

In addition, for the 2013 payment year, we are proposing to extend the use of attestation as a reporting method for the CQM component of meaningful use for the EHR Incentive Program. For 2013, EPs would be able to continue to report by attestation CQM results as calculated by CEHRT, as they did for 2011 and 2012. We refer readers to the EHR Incentive Program – Stage 1 final rule for further explanation of the CQM reporting criteria for EPs and attestation (75 FR 44386 – 44411, 44430 – 44434).

We invite public comment on our proposal to extend the PQRS-Medicare EHR Incentive Pilot and attestation as it was established for the 2012 payment year to the 2013 payment year. Please note that we are only proposing the extension of the PQRS-Medicare EHR Incentive Pilot to the 2013 payment year, because Stage 2 of the EHR Incentive Program is expected to begin in 2014. The proposals for Stage 2 of the EHR Incentive Program were provided in a standalone proposed rule published on March 7, 2012 (77 FR 13698).

## I. Medicare Shared Savings Program

### 1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment

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)).

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 of the Act, 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 (76 FR 67902). In the Shared Savings Program final rule, we finalized the following requirements with regard to PQRS incentive payments under the Shared Savings Program: (1) the 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889-67890); (2) reporting via the GPRO web interface (76 FR 67893); (3) criteria for satisfactory reporting (76 FR 67900); and (4) 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 § 425.504(a)(1), ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to qualify on behalf of their eligible professionals for the

PQRS incentive under the Shared Savings Program. ACO providers/suppliers that are eligible professionals constitute a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Under §425.504(a)(2)(ii), an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under the Shared Savings Program during the reporting period according to the method of submission established by CMS in order to receive a PQRS incentive under the Shared Savings Program. For the years in which a PQRS incentive is available, if eligible professionals that participate in an ACO as ACO providers/suppliers qualify for a PQRS incentive payment under the Medicare Shared Savings Program, the ACO participant TIN(s) under which those ACO providers/suppliers bill, will receive an incentive payment based on the allowed charges of those ACO providers/suppliers. Under §425.504(a)(4) , ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot earn a PQRS incentive outside of the Medicare Shared Savings Program. The PQRS incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B PFS allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

As discussed in section III.G of this proposed rule, as required by section 1848(a)(8) of the Act , a payment adjustment will apply under the PQRS beginning in 2015. For eligible professionals who are not satisfactory reporters, the PFS amount for covered professional services furnished by the eligible professional during 2015 shall be 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. Therefore, consistent with our authority under section 1899(b)(3)(D) of the Act, we propose to amend §425.504 to incorporate reporting requirements for the PQRS

payment adjustment under the Shared Savings Program for eligible professionals that are ACO providers/suppliers.

We are proposing to incorporate requirements for the PQRS payment adjustment that are consistent with requirements for PQRS incentives that we previously adopted in the Shared Savings Program final rule. Specifically, for purposes of the PQRS payment adjustment, we propose to incorporate the same PQRS GPRO under the Shared Savings Program that is currently used for purposes of the PQRS incentive under the Shared Savings Program. Under this proposal, eligible professionals that are ACO providers/suppliers would constitute a group practice that would report quality measures via the GPRO data collection tool for purposes of both the PQRS incentive under the Shared Savings Program and the PQRS payment adjustment under the Shared Savings Program.

For purposes of the payment adjustment, we propose to use the final GPRO quality measures adopted under the Shared Shavings Program that appear in Table 1 of the Shared Savings Program final rule (76 FR 67899-67890). We further propose to incorporate the same criteria for satisfactory reporting that were finalized for the PQRS incentive under the Shared Savings Program, which are described in the Shared Savings Program final rule (76 FR 67900). Specifically:

- An ACO on behalf of its eligible professionals must report on all measures included in the GPRO data collection tool under the Shared Savings Program final rule.
- Beneficiaries would be assigned to the ACO using the methodology described in § 425.400. As a result, the GPRO tool would be populated based on a sample of the ACO-assigned beneficiary population. ACOs must to complete the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which

they appear in the group's sample for each domain, measures set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411, the ACO must report on 100 percent of assigned beneficiaries for the domain, measures set, or individual measure.

- The GPRO data collection tool must be completed for all domains, measure sets and measures described in Table 1 of the of the Shared Savings Program final rule (76 FR 67889-67890).

Consistent with the reporting requirements for the PQRS incentive under the Shared Savings Program, ACOs would only need to satisfactorily report the 22 GPRO quality measures identified in Table 1 of the Shared Savings Program final rule (76 FR 67889-67890), and would not need to report the other 11 Shared Savings Program quality performance measures for purposes of satisfactory reporting for the PQRS payment adjustment. However, the ACO would still be required to satisfy the ACO quality performance standards for purposes of determining eligibility for shared savings, as described in §425.502.

We believe that using the same quality measures and the same criteria for satisfactory reporting, including the same assignment and sampling methodology, under the Shared Savings program for both the PQRS incentive and payment adjustment is appropriate. Aligning the satisfactory reporting requirements for the PQRS payment adjustment under the Shared Savings Program with the reporting requirements for purposes of the PQRS incentive under the Shared Savings Program would enable eligible professionals that participate in ACOs as ACO providers/suppliers to comply with these reporting requirements, without imposing any additional reporting burden. In addition, as noted above, the 22 GPRO measures that are reported for purposes of the PQRS incentive under the Shared Savings Program must also be

reported for purposes of assessing ACOs' quality performance under the Shared Savings Program and determining the percentage of shared savings that ACOs are eligible to receive. Under the Shared Savings Program regulations at §425.500(e)(3), ACOs are required to report on all of the quality measures established by CMS, and the failure to report on those quality measures accurately, completely, and timely may subject the ACO to termination or other sanctions. Thus, ACOs already have significant incentives to report the 22 GPRO measures completely and accurately. Furthermore, aligning the reporting requirements could help to encourage greater participation in the Shared Savings Program, by minimizing the reporting burden imposed upon ACOs and their participants.

Although we propose to use the same timeframe of January 1 through December 31 that we adopted for the PQRS incentive under the Shared Savings Program as the reporting period for the PQRS payment adjustment, we propose that the *timing* of the reporting period would differ for purposes of the PQRS payment adjustment. Specifically, we propose that the reporting period for the payment adjustment would fall 2 years prior to when the payment adjustment would be assessed. For example, under the Shared Savings Program, the reporting period for the 2015 payment adjustment would be from January 1, 2013 through December 31, 2013. It is necessary for us to use a reporting period that precedes the year in which the payment adjustment is applicable to avoid retroactive payments and the reprocessing of claims. In addition, it is not operationally feasible for us to use a full calendar year reporting period that falls closer to the year in which the payment adjustment is applicable because we need sufficient time to determine if the requirements for satisfactory reporting have been met and to adjust our claims systems prior to the start of the applicable year. We note that the length and timing of the reporting period that we are proposing for the PQRS payment adjustment under the Shared Savings Program is consistent with the one used for the traditional PQRS (76 FR 73392).

We also note that this proposal results in overlapping reporting periods for both the PQRS incentive and payment adjustment. For example, the measure data collected for the 2013 calendar year reporting period (January 1, 2013-December 31, 2013) would be used for purposes of both the Physician Quality Reporting System 2013 incentive and 2015 payment adjustment under the Shared Savings Program. We believe using the same reporting period for purposes of both the incentive and payment adjustment would result in less reporting burden, since one set of measures from one reporting period would be used for purposes of both the PQRS incentive and payment adjustment. We believe ACOs will perceive this as more efficient than requiring one set of measures reported during one timeframe for purposes of the PQRS incentive and another set during another timeframe for purposes of the payment adjustment.

Therefore, we propose that, if an ACO satisfactorily reports the ACO GPRO web interface measures during the applicable reporting period, its participant TINs with ACO providers/suppliers who are eligible professionals, would not be subject to the PQRS payment adjustment. If an ACO does not satisfactorily report the ACO GPRO web interface measures during the applicable reporting period, its participant TINs with ACO providers/suppliers who are eligible professionals, would be subject to the PQRS payment adjustment starting in 2015.

Since the publication of the Shared Savings Program final rule, we have received a number of inquiries regarding whether ACO participant TINs need to self-nominate or register to participate in PQRS GPRO under the Shared Savings Program, since there are such registration and self-nomination requirements under the traditional PQRS GPRO. We wish to clarify that no registration or self-nomination is required for ACO providers/suppliers that are eligible professionals to participate in PQRS under the Shared Savings Program.

Finally, just as ACO providers/suppliers that are eligible professionals with an ACO may only participate under their ACO participant TIN as a group practice under the PQRS GPRO

under the Shared Savings Program for purposes of receiving an incentive as both a group and as an individual under the same TIN (76 FR 67903), we propose that ACO providers/suppliers that are eligible professionals within an ACO must participate under the ACO participant TIN as a group practice under the PQRS GPRO under the Shared Savings Program for purposes of the PQRS payment adjustment. 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.

We recognize that some eligible professionals may move across programs and reporting options from year to year. For instance, an eligible professional that is an ACO provider/supplier and participates in the PQRS under the Shared Savings Program in 2013 may later exit the Shared Savings Program and participate in PQRS individual reporting in 2014. Alternatively, a group practice participating in the traditional PQRS GPRO in 2013 may be an ACO participant in 2014. In instances in which eligible professionals change their PQRS reporting option from year to year, we believe that as long as the eligible professional satisfactorily reported for purposes of the payment adjustment during the applicable reporting period, then the eligible professional should not be subject to the payment adjustment even if the eligible professional was reporting under a different reporting method than at the time the payment adjustment would be assessed. Using the earlier example, if an eligible professional is an ACO provider/supplier and satisfactorily reports under the PQRS under the Shared Savings Program in 2013 but subsequently exits the Shared Savings Program and participates in PQRS individual reporting in 2014, the eligible professional would not be subject to the payment adjustment in 2015. Similarly, a group practice that satisfactorily reports under the traditional PQRS GPRO in 2013 and becomes an ACO participant in 2014 would not be subject to the payment adjustment in 2015. We recognize that group practices and ACOs may reorganize and that individual providers

and groups of providers may move in and out of ACOs from year to year, so we believe this approach offers maximum flexibility for eligible professionals and groups of providers to make appropriate decisions regarding their participation in an ACO and allows ACOs to recruit new participants, by eliminating any risk that eligible professionals will be assessed with the payment adjustment as a result of such changes. We believe it would be unfair to assess the payment adjustment on an eligible professional on the basis of switching reporting options, if the eligible professional had satisfactorily reported during the applicable reporting period. We invite public comment on our proposals for Shared Savings Program ACOs and the PQRS payment adjustment and on the alternative considered.

Please note that, in this proposed rule, we also discuss a proposal amending requirements for ACO data to be publicly reported on Physician Compare in section III.G. of this proposed rule.

J. 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 2012 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately $470 million, which reflected the statutory 29.4 percent reduction to physician payments scheduled to take effect that year. As noted above, the statute was subsequently amended to impose a zero percent update for CY 2012 instead of the 29.4 percent reduction. OACT now estimates CY 2012 chiropractic expenditures to be approximately $630 million. We are currently recouping $10 million through adjustments to the chiropractic CPT codes in CY 2012, and the percent of this reduction is approximately 1.5 percent.

We are continuing the implementation of the required BN adjustment by recouping $10 million in CY 2013. Our Office of the Actuary estimates chiropractic expenditures in CY 2013 will be approximately $470 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 30.9 percent reduction to physician payments scheduled to take effect under current law. To recoup $10 million in CY 2013, the payment amount under the PFS for the chiropractic CPT codes (CPT codes 98940, 98941, and 98942) will be reduced by approximately 2 percent. We are reflecting this reduction only in the

payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the relative value units (RVUs). Avoiding an adjustment to the RVUs would preserve 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 2011-2012 PFS regulations, we are implementing this methodology and recouping from the chiropractor fee schedule codes set forth above. Our methodology meets the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration.

K. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

1. Value-based Payment Modifier and Physician Feedback Reporting Program Overview of Proposals

Section 1848(p) of the Act requires the Secretary to "establish a payment modifier that provides for differential payment to a physician or a group of physicians" under the PFS "based upon the quality of care furnished compared to cost … during a performance period." In addition, section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the payment modifier beginning January 1, 2015 to specific physicians and groups of physicians the Secretary determines appropriate. This section also requires the Secretary to apply the value-based payment modifier for all physicians and groups of physicians (and allows the Secretary to apply the value-based payment modifier for eligible professionals as defined in section 1848(k)(3)(B) of the Act as the Secretary determines appropriate) beginning not later than January 1, 2017. Section 1848(p)(4)(C) of the Act requires the value-based payment modifier to be implemented in a budget neutral (BN) manner.

Section 1848(n) of the Act requires the Secretary to provide confidential Physician Feedback reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare beneficiaries by a physician or group of physicians in those reports.

In developing our proposals for the value-based payment modifier, we have reviewed our experience over the past 3 years in providing Physician Feedback reports to certain physicians and groups of physicians. The Physician Feedback reports allow us to test different methodologies and to obtain stakeholder feedback that can be used to further refine the reports and inform our policy proposals and recommendations. We have also linked the Physician

Feedback reports with the Physician Quality Reporting System (PQRS), by including the quality measures physicians and groups of physicians reported in the PQRS program in the 2010 Physician Feedback reports that we produced and disseminated in 2011 (to groups of physicians) and early 2012 (to individual physicians).

In this proposed rule, we discuss our proposals to implement the value-based payment modifier (which will affect payments starting in 2015). These proposals focus on creating value for Medicare fee-for-service (FFS) beneficiaries by focusing on prevention and effective chronic disease care and by encouraging high quality care for the most difficult cases. The proposals recognize that physician quality measurement is still evolving and that our methodologies are still developing. We designed our proposals to (1) provide groups of physicians with 25 or more eligible professionals an option that their value-based payment modifier be calculated using a quality-tiering approach; (2) focus our payment adjustment (both upward and downward) on those groups of physicians that are outliers, that is on those that are significantly different from the mean; and (3) align the value-based payment modifier with the PQRS and utilize Medicare claims data in order to reduce administrative burden on groups of physicians. We believe that our proposals are adaptable to smaller groups of physicians and physicians in solo practices that will be subject to the value-based payment modifier starting in 2017 and we seek comment on the potential for our current proposals to be applied to all physicians and groups of physicians. We also encourage physicians and other stakeholders to work with us to include additional quality measures (including additional outcome measures) that meaningfully measure the care they provide to Medicare beneficiaries.

Our proposed scoring methodology for the value-based payment modifier would assess quality of care furnished compared to cost during the performance period (which is 2013 for the first year) to calculate an adjustment to payments under the PFS during the payment adjustment

period (which is 2015 for the first year). In light of our desire to align CMS quality improvement programs, this methodology relies, in part, on the data submitted on quality measures by groups of physicians through the PQRS. Quality measurement is necessary, but not sufficient, for quality improvement and a focus on value.[5] To balance our goals of beginning the implementation of the value-based payment modifier consistent with the legislative requirements and to give us and the physician community experience in its operation, we propose to separate all groups of physicians with 25 or more eligible professionals into two categories based on how they have chosen to participate in the PQRS.

The first category includes those groups of physicians that have met the criteria for satisfactory reporting of data on PQRS quality measures for the 2013 and 2014 incentives or the criteria for satisfactory reporting using the administrative claims-based reporting mechanism, which is applicable to the 2015 and 2016 PQRS payment adjustment. These groups of physicians will have fulfilled a key condition for quality improvement and a focus on value, that is, to measure quality by reporting data on quality measures that can be used to assess quality of care furnished. Thus, we propose initially to set the value-based payment modifier at 0.0 percent for these groups of physicians, meaning that the value-based payment modifier would not affect their payments under the PFS.

Within this category of satisfactory PQRS reporters, we propose to offer an option that their value-based payment modifier be calculated using a quality-tiering approach. This option would allow these groups of physicians to earn an upward payment adjustment for high performance (high-quality tier and low-cost tier) performance, and to be at risk for a downward payment adjustment for poor performance (low-quality tier and high-cost tier). Because of the BN requirement and proposed limit on the downward adjustment noted below, we cannot specify

[5] Mark R. Chassin, et al. "Accountability Measures – Using Measurement to Promote Quality Improvement," N Eng. J. of Med. 2010; 363:683-688 (Aug. 2010), available at http://www.nejm.org/doi/full/10.1056/NEJMsb1002320.

the exact amount of the upward payment adjustment for groups of physicians achieving high performance. We propose, however, that the maximum downward payment adjustment for these groups would be -1.0 percent for poor performance because we recognize that 2015 is the initial year for the value-based modifier and we wish to provide for a very modest adjustment for the initial years. We believe this methodology would encourage future improvement in terms of better value for Medicare beneficiaries without being overly burdensome to groups of physicians that requested to have their value-based payment modifier be calculated using the quality-tiering approach.

The second category includes those groups of physicians with 25 or more eligible professionals that have not met the PQRS satisfactory reporting criteria identified above, including those groups of physicians that have decided not to participate in any PQRS reporting mechanism. Because we would not have quality measure performance rates on which to assess the quality of care furnished by these groups of physicians, we propose to set their value-based payment modifier at -1.0 percent as described in more detail in our proposal below. We note that this downward payment adjustment for the 2015 value-based payment modifier would be in addition to the -1.5 percent payment adjustment that is assessed under section 1848(a)(8) of the Act for failing to meet the satisfactory reporting criteria under PQRS. Therefore, groups of physicians with 25 or more eligible professionals that fail to meet the PQRS satisfactory reporting criteria would be subject to a downward adjustments during 2015 of 1.5 percent for eligible professionals who fail to be satisfactory reporters under the PQRS and 1.0 percent for the value-based payment modifier. Because the value-based payment modifier provides upward payment adjustments for groups of physicians on the high-quality and lost-cost tiers, we encourage groups of physicians with 25 or more eligible professionals to elect that their value-based payment modifier be calculated using the quality-tiering approach.

In this proposed rule, we (1) expand upon our vision of how we see the value-based payment modifier helping transform Medicare from a passive payer to an active purchaser of higher quality, more efficient healthcare; (2) propose to whom the value-based payment modifier would apply starting in CY 2015 in ways that emphasize the value-based payment modifier's focus on increasing quality measurement such that all physicians and groups of physicians would be subject to value-based payment modifier starting in CY 2017; (3) propose ways to align the value-based payment modifier with the quality measures and reporting requirements established under the PQRS; (4) propose how we would score the value-based payment modifier and apply the BN requirement in ways that encourage quality reporting through the PQRS; and (5) describe how we have used and plan to continue to use the Physician Feedback reports to further inform physicians and groups of physicians about their quality of care and resource use.

2. Value-Based Payment Modifier Overview

The value-based payment modifier is an important component in revamping how care and services are paid for under the PFS that has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and effective healthcare. We recognize that although the quality of care furnished is high in many regards, this fact ignores "[h]ealth care today harms too frequently and routinely fails to deliver its potential benefits" to patients.[6] Indeed, the Institute of Medicine has stated that the "health care system as currently structured does not, as a whole, make the best use of its resources."[7] Findings from the 2010 Physician Feedback reports confirm this statement: high value (high quality and low cost)

[6] Institute of Medicine, "Crossing the Quality Chasm," (2001) at 1; Elizabeth A. McGlynn, "The Case for Keeping Quality on the Health Reform Agenda," prepared testimony before the Senate Committee on Finance (June 3, 2008), available at http://www.rand.org/content/dam/rand/pubs/testimonies/2008/RAND_CT306.pdf

[7] "Crossing the Quality Chasm" at 3.

can be achieved and there is substantial room for quality improvement and better value.[8] We believe that the value-based payment modifier can be used to incentivize and reward high quality, efficiently furnished care 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 recognize, however, that physicians are the forefront of care delivery and that changes in payment policy can directly affect medical care that physicians furnish to Medicare beneficiaries. Consistent with the National Quality Strategy, our aim is to promote preventive care and improve rather than impede the care that beneficiaries currently receive, especially for the chronically ill and those with the most complicated cases. Thus, we seek to implement payment policies that complement and support "the courage, hard work, and commitment of doctors, nurses, and others in health care" to improve the health care systems in which they work.[9]

We explained in the CY 2012 PFS proposed rule that Medicare is beginning to implement value-based payment adjustments for other types of services, including inpatient hospital services (76 FR 42908). We have also developed plans to implement value-based purchasing for skilled nursing facilities, home health services and ambulatory surgical center services. In implementing value-based purchasing initiatives generally, we seek to meet the following goals:

- Recognize and reward high quality care and quality improvements.

++ Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and

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[8] CMS, "Analysis of 2010 Quality and Resource Use Reports for Medical Practice Groups" (2012), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/QRURs_for_Medical_Practice_Groups.pdf

[9] "Crossing the Quality Chasm" at 4.

changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, we believe these outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

++ To the extent possible, and recognizing differences in payment system readiness and statutory requirements and authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve a focused core set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

++ The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

++ To the extent practicable, the measures we use should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

● Promote more efficient and effective care through the use of evidence based measures, less rework and duplication, and less fragmented care.

++ Providers should be accountable for the costs of care, being both rewarded for reducing unnecessary expenditures and responsible for excess expenditures.

++ In reducing excess expenditures, providers should continually improve and maintain the quality of care they deliver.

++ To the extent possible, and recognizing differences in payers' value based purchasing initiatives, providers should redesign care processes to deliver higher quality and more efficient

care to their entire patient population.

Because of the centrality of physicians to high-quality, efficient, patient-centered care furnished in multiple settings, we believe that in the long run the value-based payment modifier should rely on measuring physician performance (both quality of care and cost) at four levels (to the extent practicable) – the individual physician level, the group practice level, the facility level (for example, hospital), and the community level. Physicians make decisions on a patient-by-patient basis as to what services are indicated and furnished. These decisions are made independently by physicians within multiple settings (that is, individual office practice, group practice, hospital) and are dependent, in part, on how care is organized in a community. Consequently, physicians have the potential to drive both quality of care and costs at all levels of the health system and these decisions have an impact on patient outcomes and costs for populations of patients. We envision a physician value-based payment modifier in the future that blends performance at each of these levels (as applicable) and reinforces our objectives to encourage and reward physicians for furnishing high-quality, efficient, patient-centered clinical care.

To start to implement this long-term vision of the value-based payment modifier, we have undertaken numerous activities in the past year to inform our proposals in this rule. We have obtained stakeholder input about the content (including the completeness of the quality measures) and methodologies we have used in the Physician Feedback reports, as well as input on how the private sector has used physician pay-for-performance programs. In particular, we conducted five national provider calls about methodologies we have used in the Physician Feedback reports and similar private sector initiatives.[10] We also held (and continue to hold)

[10] See CMS, Physician Feedback Program Teleconferences and Events, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/CMS-Teleconferences-and-Events.html

numerous sessions with Physician Feedback report recipients (both at the individual and group practice level) to obtain additional feedback to improve the methodologies used in the reports.

These recent activities complement the work we have undertaken to implement the statutory objectives to improve quality of care furnished by physicians and groups of physicians to Medicare beneficiaries. For example, the Congress required the Physician Group Practice (PGP) Demonstration, which we implemented in 2005. The PGP Demonstration was the first pay-for-performance initiative under the Medicare program that involved a shared savings model. The demonstration created incentives for physician groups to coordinate the overall care furnished to Medicare beneficiaries and rewarded them for improving the quality and cost efficiency of health care services. By the fifth year of the demonstration, all 10 of the participating physician groups achieved quality benchmark performance on at least 30 of the 32 measures, and seven of the groups achieved benchmark performance on all 32 performance measures. The PGP quality reporting tool and its methodology also became the basis for the Group Practice Reporting Option (GPRO) under the PQRS.

In 2003, we implemented the Medicare Care Management Performance (MCMP) demonstration project. The demonstration showed that small and solo physician practices are willing to participate in quality measurement and reporting. Almost 700 physician practices of various sizes used a GPRO-like reporting tool to report data on 23 quality measures.

In 2006, Congress established what is now known as the Physician Quality Reporting System (PQRS), which is a voluntary quality reporting program that, as subsequently amended, provides a combination of incentive payments and payment adjustments to eligible professionals (including group practices) based on whether they satisfactorily report data on quality measures for covered professional services furnished to Medicare Part B FFS beneficiaries. In 2010,

268,968 eligible professionals[11] participated in PQRS in addition to those physicians participating in quality reporting through the PQRS GPRO option.

Recently, we provided physicians and groups of physicians with confidential Physician Feedback reports that provide them with comparative performance data on quality of care they furnish compared to costs. Results from the most recent group practice reports show little correlation between quality of care furnished and cost for the 35 participating group practices to whom we provided reports--high quality can be associated with high or low cost (and vice versa) (see Physician Feedback Program discussion below). Moreover, overall results from the individual Physician Feedback reports based on 2010 data show that clinical care is highly fragmented and there is substantial room for improvement in the quality of care furnished to Medicare fee for service beneficiaries.

Based on what we have learned from the aforementioned demonstration projects, the results from the PQRS and the confidential Physician Feedback reports, and our outreach on the national provider calls on private sector programs, we believe the value-based payment modifier and the Physician Feedback reports can be used to incentivize and reward high quality, efficiently furnished care by providing upward payment adjustments under the PFS to high performing physicians and downward adjustments for low performing physicians. To do so, we believe the following specific principles should govern the implementation of the value-based payment modifier.

- A focus on measurement and alignment. It is difficult to maintain high quality care and improve quality and performance without measurement. Therefore, the value-based payment modifier should incorporate performance on more quality measures than those that we finalized in the CY 2012 PFS final rule (76 FR 73429 through 73432). These additional

[11] Eligible professionals include physicians and non-physicians such as physician assistants and nurse practitioners.

measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups and reflect the diversity of services furnished. These measures should 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. In the proposals described later in this section, we propose to expand the quality measures for the value-based payment modifier. We also encourage physicians to work with us to include additional quality measures (including outcome measures) that meaningfully measure the care they furnish to Medicare beneficiaries.

- A focus on physician choice. Physicians should be able to choose the level at which their 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, such as the PQRS and the Medicare EHR Incentive program to reduce administrative burden and encourage greater program participation. In the proposals described later in this section, we propose to rely on the quality measure data collected through the PQRS Group Practice Reporting Option (GPRO) and Medicare EHR Incentive Program to obtain most of the performance data for the value-based payment modifier.

- A focus on shared accountability. CMS has a role in fostering high value care for individual patients, but also focusing on how that patient interacts with the health care system generally. We believe that the value-based payment modifier can facilitate shared accountability by assessing performance at the practice group level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician. In the proposals described later in this section, we propose to use performance on several outcome measures that we will calculate for physicians reporting measures at the group level that encourage them to seek innovative ways

to furnish high-quality, patient-centered, and efficient care to the Medicare FFS patients they treat. We also seek to start a discussion on how best to incorporate individual, hospital-based, and community-based quality and cost measures as a component of the value-based payment modifier so that we align quality measurement strategies across providers and settings of care.

- A focus on actionable information. In conjunction with adjusting payment based on performance, CMS should provide meaningful and actionable information to help physicians identify clinical areas where they are doing well as well as areas in which performance could be improved. The Physician Feedback reports can serve this purpose. In the proposals described later in this section, we propose ways to provide additional feedback to physicians and groups of physicians through the Physician Feedback reports.

- A focus on a gradual implementation. We believe that the value-based payment modifier should focus initially on outliers (that is, those groups of physicians that are demonstrably high or low performers as compared to their peers that treat like beneficiaries). We also believe that groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in 2015 as we phase in the value-based payment modifier. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed to organize them around medical condition, refine physician peer groups to focus on how like beneficiaries are treated, create finer payment distinctions that focus on increasing value, and provide greater payment incentives for high performance. In the proposals described later in this section, we propose to allow groups of physicians with 25 or more eligible professionals to elect how the value-based payment modifier would be applied to them under the PFS starting in 2015. We also propose a scoring methodology that can identify outliers (both high and low performers) and is flexible to accommodate these future goals.

We seek comment on these principles as guides to our implementation of the value-based payment modifier.

3. Proposals for the Value-Based Payment Modifier

In the following sections, we describe our proposals for each component of the value-based payment modifier. These components include: the quality measure reporting methods; the quality and cost measures; the attribution methodology; the payment adjustment amount; the scoring methodology; and the review and inquiry process. Following the discussion of these components, we summarize how the components would work together for a group of physicians with 25 or more eligible professionals that submits data on quality measures using the PQRS GPRO web-interface and requests that their value-based payment modifier be calculated using the quality-tiering approach.

a. Proposed Application of the Value-Based Payment Modifier

Section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the value-based payment modifier to items and services furnished beginning on January 1, 2015, for specific physicians and groups of physicians the Secretary determines appropriate, and beginning not later than January 1, 2017 for all physicians and groups of physicians. For purposes of this proposed rule, physicians are defined in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

We propose to initially include all groups of physicians with 25 or more eligible professionals in the value-based payment modifier. For purposes of establishing group size, we propose to use the definition of an eligible professional as specified in section 1848(k)(3)(B) of the Act. This section defines an eligible professional as any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational

therapist or a quality speech-language pathologist; or (4) a qualified audiologist. In addition, we propose to define a group of physicians as "a single Tax Identification Number (TIN) with 25 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN." We chose these groups of physicians in order to align with the reporting requirements for group practices and the definitions used in the PQRS. We also propose to assess whether a group of physicians has 25 or more eligible professionals at the time the group of physicians is selected to participate under the PQRS GPRO.

We propose to 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 or coinsurance would not be affected. We also propose to apply the value-based payment modifier to the items and services billed by eligible professionals who are physicians under the TIN, not to other eligible professionals that also may bill under the TIN.

In addition, application of the value-based payment modifier at the TIN level means that we would not "track" or "carry" a physician's performance from one TIN to another TIN. In other words, if a physician changes groups from TIN A in the performance period (2013) to TIN B in the payment adjustment period (2015), we would apply TIN B's value-based payment modifier to the physician's payments for items and services billed under TIN B during 2015. We are making this proposal for two reasons. First, payment at the group practice (TIN level) reflects the view that the group in which a physician practices matters. Second, we believe it will be more straightforward for groups of physicians to understand how the value-based payment modifier affects their TIN's payment in the payment adjustment period if all physician billing under the TIN receive the same value-based payment modifier. We seek comment on these proposals.

It is critical to note that our proposals would allow groups of physicians with 25 or more eligible professionals to decide how the value-based payment modifier would be applied to their PFS payments. In light of our desire to align CMS quality improvement programs, this methodology relies, in part, on the data submitted on quality measures by groups of physicians through the PQRS. Quality measurement is necessary, but not sufficient, for quality improvement and a focus on value. We propose to separate all groups of physicians with 25 or more eligible professionals into two categories based on how they have chosen to participate in the PQRS.

The first category includes those groups of physicians with 25 or more eligible professionals that have met the proposed criteria for satisfactory reporting of data on PQRS quality measures for the 2013 and 2014 incentive or the proposed criteria for satisfactory reporting using the administrative claims-based reporting mechanism, which is applicable to the 2015 and 2016 PQRS payment adjustment. These groups of physicians will have fulfilled a key condition for quality improvement and a focus on value, that is, to measure quality by submitting and/or having data on quality measures that can then be used to assess quality of care furnished. We propose initially to set the value-based payment modifier at 0.0 percent for these groups of physicians, meaning that the value-based payment modifier would not affect their payments under the PFS. We point out that in order for a group of physicians to meet the satisfactory reporting criteria, the group of physicians must first self-nominate as a group as described above in Section III.G.1.b.2 of this proposed rule regarding the PQRS.

Within this category of satisfactory PQRS reporters, we propose to offer an option that their value-based payment modifier be calculated using the quality-tiering approach described below in subsection (h) Proposed Value-Based Payment Modifier Scoring Methodology. Under these proposals, groups of physicians could earn an upward payment adjustment for high

performance (high-quality tier compared to low-cost tier) performance, and be at risk for a downward payment adjustment for poor performance (low-quality tier compared to high-cost tier). We seek comment, however, on whether to calculate the value-based payment modifier for all groups of physicians that are satisfactory PQRS reporters using the quality-tiering approach described in subsection (h) below, rather than providing an option for such groups of physicians to request that we do so.

The second category includes those groups of physicians with 25 or more eligible professionals that have not met the PQRS satisfactory reporting criteria identified above. Under our proposal, a group of physicians could fail to meet the PQRS satisfactory reporting criteria because the group of physician decided not to participate in any PQRS reporting mechanism or because the group attempted to submit data, but failed to meet the criteria to become a satisfactory reporter (e.g., did not report data appropriately on the requisite number of beneficiaries or measures). Because we would not have quality measure performance rates on which to assess the quality of care furnished by these groups, we propose to set their value-based payment modifier at -1.0 percent, meaning they would receive 99.0 percent of the paid amounts for the items and services billed under the PFS.

We believe this approach is a reasonable way to phase in the value-based payment modifier because groups of physicians have demonstrated their ability to submit data on quality measures at the group level using the PQRS GPRO since 2011. And for 2012, we revised the eligibility criteria for the PQRS GPRO to include groups with at least 25 eligible professionals. Thus, we believe that these groups of physicians have had sufficient opportunity to make an informed decision about submitting data on quality measures that also could be used in the value-based payment modifier starting in 2015.

Moreover, section 1848(p)(5) of the Act requires us to, as appropriate, apply the value-

based payment modifier "in a manner that promotes systems-based care." In this context, systems-based care is the processes and workflows that (1) make effective use of information technologies, (2) develop effective teams, (3) coordinate care across patient conditions, services, and settings over time, and (4) incorporate performance and outcome measurements for improvement and accountability.[12] We believe that groups of physicians have the ability and the resources to redesign such processes and workflows to achieve these objectives and furnish high-quality and cost-effective clinical care.

Starting in 2017, we would apply the value-based payment modifier to all physicians and groups of physicians as required by the statute. We seek comment on whether we should offer individual physicians and groups of physicians with fewer than 25 eligible professionals an option that their value-based payment modifier be calculated using a quality-tiering approach starting in 2015. If we did so, we could calculate a value-based payment modifier for groups of physicians with as few as two eligible professionals and apply the value-based payment modifier at the TIN level in the manner described in these proposals for groups of 25 or more eligible professionals. Likewise, we seek comment on how to adapt our proposals to calculate a value-based payment modifier at the TIN level for physicians in solo practices (TINs comprised of one NPI).

We also seek comment on whether we should develop a value-based payment modifier option for hospital-based physicians to elect to be assessed based on the performance of the hospital at which they are based. In particular, hospital performance could be assessed using the measure rates the hospitals report on the quality measures in the Inpatient Quality Reporting (IQR) and the Outpatient Quality Reporting (OQR) programs. If so, we seek comment on which

[12] Johnson JK, Miller SH, Horowitz SD. Systems-based practice: Improving the safety and quality of patient care by recognizing and improving the systems in which we work. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches, Vol 2: Culture and Redesign. AHRQ Publication No. 08-0034-2. Rockville, MD: Agency for Healthcare Research and Quality; August 2008. p. 321-330.

IQR and OQR measures (and the applicable reporting period) would be appropriate to include in such an option and a way to identify and verify whether physicians are hospital-based. The IQR measures can be found at http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1141662756099 and the OQR measures can be found at http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244.

In addition, we seek comment on how best to ascertain whether a group of physicians with 25 or more eligible professionals requests the option that their value-based payment modifier be calculated using a quality-tiering approach. We seek to establish a system that reduces administrative burden on physicians, enables these groups of physicians to indicate how they plan to submit data on quality measures through the PQRS, and is easy to administer. We could, for example, build off of the self-nomination process that we have proposed for groups of physicians to participate in the PQRS GPRO. As discussed in Section III.G.1.b.2 of this proposed rule regarding the PQRS, we anticipate that we will have the ability to collect self-nomination statements via the web in 2013. As proposed above, these self-nomination statements would be submitted by January 31, 2013 for the 2013 performance period. In the event that the web-based functionality is unable to accept self-nomination statements for 2013, we have proposed that groups of physicians submit a self-nomination statement via a letter (in a prescribed format) to CMS in a timely manner.

We also could establish a separate web-based registration system that permits groups of physicians to , throughout calendar year 2013, request that their value-based payment modifier be calculated using the quality-tiering approach (rather than submit a self-nomination statement by January 31, 2013 as proposed in the PQRS self-nomination process). Another approach

would be to require that groups of physicians submit a letter (in a prescribed format) to CMS in a timely manner. We seek comment on these approaches.

We propose not to offer groups of physicians with 25 or more eligible professionals that are participating in the Medicare Shared Savings Program or are associated with the Pioneer ACO program, assuming they meet the PQRS satisfactory reporting criteria, the option that their value-based payment modifier be calculated using the quality-tiering approach. As of April 2012, 27 ACOs are participating in the Shared Savings Program, and 32 ACOs are participating in the Pioneer ACO program. We anticipate more ACOs will enter the Medicare Shared Savings Program beginning July 1, 2012, and on January 1st annually thereafter. Shared Savings Program ACOs will be in a "pay for reporting" mode in 2013, while Pioneer ACOs will be in a "pay for performance" mode in 2013.

We make this proposal because we are mindful that the physicians and groups of physicians that are, or will be, participating in the Shared Savings Program and the Pioneer ACO program have made sizable investments to redesign care processes based on the incentives created by these programs. Indeed, these organizations have committed to reporting on a broader set of quality measures than we are proposing for the value-based payment modifier to demonstrate the quality of care their beneficiaries are receiving. We do not wish to unintentionally disturb these investments. Therefore, we seek comment on ways to structure the value-based payment modifier starting in 2017 so it does not create incentives that conflict with the goals of the Shared Savings Program and the Pioneer ACO program. Alternatively, we seek comment on whether we should permit groups of physicians that are participating in these two programs the option that their value-based payment modifier be calculated using a quality-tiering approach and applied to their payments under the PFS starting in 2015.

We note that the value-based payment modifier is applicable only to payment for

physicians' services under the PFS. The value-based payment modifier does not apply to services that physicians furnish in Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), and Critical Access Hospitals (CAHs) billing under method II (but not method I or the standard method), because they are not considered as being paid under the PFS.

b. Proposed Performance Period

We previously finalized CY 2013 as the initial performance period for the value-based payment modifier that will be applied in CY 2015 (76 FR 73436). This means that we will use performance on quality and cost measures during CY 2013 to calculate the value-based payment modifier that we would apply to items and services for which payment is made under the PFS during CY 2015. Likewise, we propose that performance in CY 2014 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.

As we explained previously in the CY 2012 PFS final rule with comment period (76 FR 73435), we explored different options to close the gap between the performance period (that is, 2013) and the payment adjustment period (that is, 2015), but that none of them would have permitted sufficient time for physicians and groups of physicians to report measures or have their financial performance measured over a meaningful period, or for us to calculate a value-based payment modifier and notify physicians and groups of physicians of their quality and cost performance and value-based payment modifier prior to the payment adjustment period. We also explained that a system that adjusted payments to take into account the value-based payment modifier after claims have been paid would be onerous on physicians and beneficiaries. We continue to explore ways to provide more timely feedback to physicians and to narrow the gap between the performance period and the payment adjustment period and seek comment on practical alternatives that we could implement to do so. We seek comment on our

proposal to use CY 2014 as the performance period for the 2016 value-based payment modifier.

c. Proposed Quality Measures

In this section we discuss our proposals to align quality measure reporting for the value-based payment modifier with PQRS reporting methods, to expand the range of quality measures that we will use for the value-based payment methodology, and to start a discussion on how to assess community based quality of care.

(1) Alignment of Quality Reporting Options with PQRS Satisfactory Reporting Criteria

As discussed above, we propose to categorize groups of physicians with 25 or more eligible professionals into two categories depending upon whether they have met the PQRS satisfactory reporting criteria established above for the value-based payment modifier. We note that under those proposed criteria for satisfactory reporting, groups of 25 or more eligible professionals would be able to submit data on quality measures using one of following proposed PQRS reporting mechanisms: PQRS GPRO using the web-interface, claims, registries, or EHRs; or PQRS administrative claims-based option. These reporting mechanisms are discussed above in Section III.G of this proposed rule (Physician Payment, Efficiency, and Quality Improvement – Physician Quality Reporting System). The satisfactory reporting criteria for the PQRS GPRO reporting mechanisms are described in Tables 27 and 28. The satisfactory reporting criteria for the PQRS administrative claims-based reporting option is described in Section III.G. ("Proposed Criteria for Satisfactory Reporting for the 2015 and 2016 Payment Adjustments for Eligible Professionals and Group Practices using the Administrative Claims-based Reporting Mechanism.") We propose to rely on these proposed criteria for satisfactory reporting in order to categorize groups of physicians for purposes of the value-based payment modifier.

For those groups of physicians that have met the PQRS satisfactory reporting criteria and request that their value-based payment modifier be calculated using a quality-tiering approach,

we propose to use the performance rates on the quality measures reported through any of these reporting mechanisms. We seek comment on this proposal. We are concerned, however, that some groups of physicians may attempt to submit data on PQRS quality measures using one of the GPRO reporting mechanisms (web-interface, claims, registries, or EHRs) and fail to meet the criteria for satisfactory reporting and thus be categorized as non-PQRS reporters (and be subject to the -1.0 percent downward adjustment). To address this issue, we seek comment on whether to assess performance on the measures included in the PQRS administrative claims-based reporting option as a default if a group of physicians attempts to participate in one of the PQRS GPRO reporting mechanisms and does not meet the PQRS criteria for satisfactory reporting.

In addition, we seek comment on which PQRS reporting mechanisms we should offer to individual physicians if we were to apply the value-based payment modifier applied to their payments under the PFS starting in 2015 or 2016. Tables 25 and 26 describe the proposed PQRS reporting options available to individual physicians for the 2013 and 2014 PQRS incentives.

(2) Quality Measure Alignment with the Physician Quality Reporting System

In the CY 2012 PFS final rule with comment period (76 FR 73432), we finalized, for physicians practicing in groups, all measures in the GPRO of PQRS for 2012. We also stated that we expected to update these measures for the initial performance year (CY 2013) of the value-based payment modifier based on the measures finalized in subsequent rulemaking under PQRS. (76 FR 73427 through 73432). We propose to include all individual measures in the PQRS GPRO web-interface, claims, registries, and EHR reporting mechanisms for 2013 and beyond for the value-based payment modifier. These quality measures are included in Tables 30 and 32. We seek comment on this proposal.

We also seek comment on the quality measures that we should propose for individual physicians if we were to provide individual physicians the ability to elect to have the value-based

payment modifier apply to their payments under the PFS starting in 2015 or 2016. In the CY 2012 PFS final rule with comment period, we finalized for individual physicians, the PQRS core set of measures for CY 2012 and the core set of measures, alternate core, and additional measures in the Medicare EHR Incentive Program for 2012. We seek comment on which PQRS measures for 2013 and beyond to include in calculating the value-based payment modifier at the individual level. Table 32 lists the PQRS measures we are proposing for reporting through PQRS for 2013 and beyond. We believe incorporating all the PQRS measures provides a broad set of quality measures from which physicians can choose how best to assess their performance. We seek comment on these issues and the above proposals.

(3) Administrative Claims Option under PQRS

Under the PQRS, we propose to provide an option for physicians and groups of physicians to select an administrative claims-based reporting option for purposes of the PQRS payment adjustment for 2015 and 2016 only. We discuss two issues surrounding this proposed administrative claims-based reporting option as it relates to the value-based payment modifier: (1) the level at which to assess the administrative claims-based measures (individual or group), and (2) the scope of quality measures that will be assessed using administrative claims.

(a.) Level of Performance Assessment

We can either assess performance at the individual physician level, as we did in the 2010 individual Physician Feedback reports, or at the group practice level and apply the performance rate to the physicians that are part of that group. Measurement and assessment at the individual level (as identified by a National Provider Identification number (NPI)) provides actionable information for improvement for physicians and can incentivize physician accountability for quality of care and cost. Despite these benefits, assessments of individual physicians using administrative claims-based measures may result in insufficient numbers of cases at the

individual level to develop statistically reliable performance rates for each measure. Moreover, because physician performance would affect payment, we believe performance rates should be statistically reliable.

Assessment of physician performance at the group practice level (as identified by a single Taxpayer Identification Number (TIN)) reflects the view that the group in which a physician practices matters.[13] Group practice assessments will allow for a larger number of cases to assess performance scores and a larger number of outcome measures than assessments solely at the individual level. The larger number of cases also means the performance scores will be more statistically reliable on which to modify payment. It also allows us to calculate more quality measures in more domains of the National Quality Strategy. For these reasons, for purposes of the value-based payment modifier, we propose to assess performance rates for the measures in the PQRS administrative claims-based reporting option at the TIN level and apply the calculated performance score and the resulting value-based payment modifier to all physicians that bill under that TIN during the payment adjustment period. We seek comment on this proposal.

(b.) Quality Measures

In the CY 2010 individual Physician Feedback reports, which we distributed to over 23,000 physicians in Iowa, Kansas, Missouri, and Nebraska in March 2012, we provided performance rates on 28 administrative claims-based measures. These measures focused on clinical care of prevalent and chronic diseases among Medicare beneficiaries and medication management measures and were assessed at the individual physician level (that is, NPI). Twenty-seven of the 28 measures were endorsed by the National Quality Forum and the remaining measure was developed and is maintained by the National Committee for Quality

[13] See e.g., Johnson JK, Miller SH, Horowitz SD. Systems-based practice: Improving the safety and quality of patient care by recognizing and improving the systems in which we work. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches, Vol 2: Culture and Redesign. AHRQ Publication No. 08-0034-2. Rockville, MD: Agency for Healthcare Research and Quality; August 2008. p. 321-330.

Assurance (NCQA). Specifications for all 28 administrative claims-based measures can be found at https://www.cms.gov/physicianfeedbackprogram.

We propose to include, for purposes of assessing performance for the PQRS administrative claims-based reporting option, 15 of these measures, which are indicated in Table 64. We have selected these 15 measures because they are clinically meaningful, focus on highly prevalent conditions among beneficiaries, have the potential to differentiate physicians, and are reliable. Most of the proposed measures do not rely on the use of Part D drug data that we do not have for all Medicare FFS beneficiaries. We also note that these proposed measures are similar to the measures adopted in several private sector programs.[14] We also seek comment, however, on whether to include any of the remaining 13 measures that we have not proposed, but included in the Physician Feedback Reports. These measures are listed in Table 65.

**TABLE 64: Proposed Measures for the Administrative Claims Option for 2015 and 2016**

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| 0576 | **Follow-Up After Hospitalization for Mental Illness**<br>Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner | NCQA | Care Coordination |
| 0021 | **Annual Monitoring for Beneficiaries on Persistent Medications**<br>Percentage of patients 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. | NCQA | Patient Safety |
| 0555 | **Lack of Monthly INR Monitoring for Beneficiaries on Warfarin**<br>Average percentage of 40-day intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period. | CMS | Patient Safety |
| 0577 | **Use of Spirometry Testing to Diagnose COPD**<br>Percentage of patients at least 40 years old who have a new diagnosis or newly active chronic obstructive pulmonary disease (COPD) who received appropriate spirometry testing to confirm the diagnosis. | NCQA | Clinical Care |
| 0549 | **Pharmacotherapy Management of COPD Exacerbation**<br>Percentage of chronic obstructive pulmonary disease (COPD) exacerbations for patients 40 years of age and older who had an acute inpatient discharge or ED encounter between January 1–November 30 of the measurement year and were dispensed appropriate medications | NCQA | Clinical Care |
| 0543 | **Statin Therapy for Beneficiaries with Coronary Artery Disease**<br>Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease. | CMS | Clinical Care |
| 0583 | **Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications**<br>Percentage of patients age 18 or older starting lipid-lowering medication during the measurement year who had a lipid panel checked within 3 months after starting drug therapy | Resolution Health | Clinical Care |
| 0053 | **Osteoporosis Management in Women ≥ 67 Who Had a Fracture**<br>Percentage of women 67 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six | NCQA | Clinical Care |

[14] Zirui Song, et al, "Health Care Spending and Quality in Year 1 of the Alternative Quality Contract," New England Journal of Medicine, 365:10 (Sept. 2011).

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| | months after the date of fracture. | | |
| 0055 | **Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes**<br>Percentage of adult patients with diabetes aged 18-75 years who received a dilated eye exam by an ophthalmologist or optometrist during the measurement year, or had a negative retinal exam (no evidence of retinopathy) by an eye care professional in the year prior to themeasurement year. | NCQA | Clinical Care |
| 0057 | **HbA1c Testing for Beneficiaries ≤ 75 with Diabetes**<br>Percentage of adult patients with diabetes aged 18-75 years receiving one or more A1c test(s) per year. | NCQA | Clinical Care |
| 0062 | **Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes**<br>Percentage of adult diabetes patients aged 18-75 years with at least one test nephropathy screening test during the measurement year or who had evidence existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria). | NCQA | Clinical Care |
| 0063 | **Lipid Profile for Beneficiaries ≤ 75 with Diabetes**<br>Percentage of adult patients with diabetes aged 18-75 who had an LDL-C test performed during the measurement year. | NCQA | Clinical Care |
| 0075 | **Lipid Profile for Beneficiaries with Ischemic Vascular Disease**<br>Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) from January 1–November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to measurement year, who had a complete lipid profile during the measurement year. | NCQA | Clinical Care |
| 0105 | **Antidepressant Treatment for Depression**<br>Percentage of discharges for patients who were hospitalized for treatment of selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner. | NCQA | Clinical Care |
| 0031 | **Breast Cancer Screening for Women ≤ 69**<br>Percentage of eligible women 40-69 who receive a mammogram in during the measurement year or in the year prior to the measurement year. | NCQA | Clinical Care |

## TABLE 65: Remaining Measures Not Proposed for the Administrative Claims Option

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| Not NQF Endorsed | **Potentially Harmful Drug-Disease Interactions in the Elderly**<br>The percentage of Medicare members 65 years of age and older who have evidence of an underlying disease, condition or health concern and who were dispensed an ambulatory prescription for a contraindicated medication, concurrent with or after the diagnosis. | NCQA | Patient Safety |
| 0071 | **Acute Myocardial Infarction (AMI): Persistence of Beta-Blocker Treatment After a Heart Attack**<br>Percentage of patients age 18 years and older during the measurement year who were hospitalized and discharged alive with a diagnosis of acute myocardial infarction (AMI) and who received persistent beta-blocker treatment for six months after discharge | NCQA | Clinical Care |
| 0022 | **Use of High-Risk Medications in the Elderly: (a) Patients Who Receive At Least One Drug To Be Avoided**<br>Percentage of patients ages 65 years and older who received at least one high-risk medication in the measurement year<br>**(b) Patients Who Receive At Least Two Different Drugs To Be Avoided**<br>Percentage of patients 65 years of age and older who received at least two different high-risk medications in the measurement year | NCQA | Patient Safety |
| 0556 | **INR for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications**<br>Percentage of episodes with an INR test performed 3 to 7 days after a newly-started interacting anti-infective medication for Part D beneficiaries receiving warfarin | CMS | Patient Safety |
| 0568 | **Appropriate Follow-Up for Patients with HIV**<br>Percentage of patients diagnosed with HIV who received a CD4 count and an HIV RNA level laboratory test in the 6 months following diagnosis | Health Benchmarks | Clinical Care |
| 0623 | **Breast Cancer – Cancer Surveillance**<br>Percentage of female patients 18 and older with breast cancer who had breast cancer surveillance in the past 12 months | Active Health Management | Clinical Care |

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| 0625 | **Prostate Cancer – Cancer Surveillance**<br>Percentage of males with prostate cancer that have had their PSA monitored in the past 12 months | Active Health Management | Clinical Care |
| 0054 | **Arthritis: Disease Modifying Antirheumatic Drug (DMARD) Therapy in Rheumatoid Arthritis**<br>Percentage of patients 18 years and older, diagnosed with rheumatoid arthritis who have had at least one ambulatory prescription dispensed for a DMARD | NCQA | Clinical Care |
| 0581 | **Deep Vein Thrombosis Anticoagulation At Least 3 Months**<br>Percentage of patients diagnosed with a lower extremity DVT more than 3 months prior to the end of the measurement year (who do not have contraindications to warfarin therapy and who do not have an IVC filter in the 90 days after the onset of PE) who had at least 3 months of anticoagulation after the event or patients showing compliance with anticoagulation therapy as indicated by a Home PT Monitoring device or multiple instances of prothrombin time testing over the 3-month period | Resolution Health | Clinical Care |
| 0593 | **Pulmonary Embolism Anticoagulation At Least 3 Months**<br>Percentage of patients diagnosed with a PE more than 3 months prior to the end of the measurement year (who do not have contraindications to warfarin therapy and who do not have an IVC filter in the 90 days after the onset of PE) who had at least 3 months of anticoagulation after the event or patients showing compliance with anticoagulation therapy as indicated by a Home PT Monitoring device or multiple instances of prothrombin time testing over the 3-month period | Resolution Health | Clinical Care |
| 0614 | **Steroid Use – Osteoporosis Screening**<br>Percentage of patients, 18 and older, who have been on chronic steroids for at least 180 days in the past 9 months and who had a bone density evaluation or osteoporosis treatment | Active Health Management | Clinical Care |
| 0567 | **Appropriate Work-Up Prior To Endometrial Ablation Procedure**<br>Percentage of women who had an endometrial ablation procedure during the measurement year who received endometrial sampling or hysteroscopy with biopsy during the previous year | Active Health Management | Clinical Care |
| 0584 | **Hepatitis C: Viral Load Test**<br>Percentage of patients 18 years or older with Hepatitis C (HCV) who began HCV antiviral therapy during the measurement year and had HCV Viral Load testing prior to initiation of antiviral therapy | Resolution Health | Clinical Care |

(4) Outcome Measures for Groups of Physicians

We finalized in the CY 2012 PFS final rule (76 FR 73432) for physicians practicing in groups to include the rates of potentially preventable hospital admissions for two ambulatory care sensitive conditions (ACSCs) at the group practice level: heart failure; and chronic obstructive pulmonary disease. We also noted that several commenters to the CY 2012 proposed PFS rule expressed support for using outcome measures that assess the rate of potentially preventable hospital admissions including the Consumer-Purchaser Disclosure Project, a group of large purchasers of health care services. We believe it is appropriate to focus on potentially preventable hospital admissions because, as our 2010 Physician Feedback reports have shown, hospital inpatient, outpatient, and emergency department costs account for over 50 percent of total per capita costs. Thus, we propose to include four outcome measures in the value-based

payment modifier for all groups of physicians with 25 or more eligible professionals. These outcome measures are discussed below. It is important to note that we propose to calculate these measures for groups of physicians with 25 or more eligible professionals regardless of which reporting mechanisms the groups of physicians choose to report quality data: PQRS GPRO using the web-interface, claims, registries, or EHRs; or the PQRS administrative claims-based reporting option.

Currently the Physician Feedback reports that we provide to group practices include potentially preventable hospital admission measures for three chronic conditions: heart disease, chronic pulmonary obstructive disease, and diabetes (a composite measure including uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes). In addition, the Physician Feedback reports provide potentially preventable hospital admission measures for three acute conditions: dehydration; urinary tract infection; and bacterial pneumonia. Specifications for all six of these measures can be found at http://www.qualityindicators.ahrq.gov/Modules/PQI_TechSpec.aspx.

However, given the potential that any group of physicians may have relatively few potentially preventable hospital admissions for a given condition, we propose to create for the value-based payment modifier two composites from these measures: an acute condition composite; and a chronic care composite. Compositing measures is a well-established technique in quality measurement to increase reliability when the number of cases is small because it combines individual measures into one composite measure. Additionally, presenters on the National Provider Calls CMS held on February 29 and March 14 entitled "Physician Value-Based Payment Modifier Program: Experience from Private Sector Physician Pay-for-Performance Programs" specifically recommended this approach for the value-based payment modifier. (Transcripts and slides from these presentations are available at

http://www.cms.gov/physicianfeedbackprogram.)

We propose that the acute condition composite combine the rates of potentially preventable hospital admission for dehydration, urinary tract infection, and bacterial pneumonia. We propose that the chronic care composite combine the rates of potentially preventable hospital admissions for diabetes, heart failure, and chronic obstructive pulmonary disease. We believe group practices will be incentivized to prevent these types of hospital admissions, which will improve patient care and reduce per capita costs.

We also propose to use two other quality measures to assess care coordination at the group level that we currently use in other CMS physician quality programs: the all-cause hospital readmission measure used in the Medicare Shared Savings Program (described on the CMS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_QualityMeasures.pdf) and the 30-day post-discharge visit measure used in the PGP Transition Demonstration (described at https://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads//PGP_Transition_Quality_Specs_Report.pdf). We believe that the all-cause hospital readmission measure provides a strong incentive for groups to focus on reducing hospital readmissions. In addition, the 30-day post-discharge visit measure helps incentivize physicians to engage in more effective care coordination. Recent literature cites a study in which there was no visit to a physician's office between the time of discharge and rehospitalization for 50 percent of patients who were rehospitalized within 30 days after a medical discharge to the community.[15] Based on input and comments from stakeholders, including other payers, we believe that such follow up visits can reduce unnecessary rehospitalizations. These four measures are summarized in Table 66.

**TABLE 66: Four Outcome Measures for the Value-Based Payment Modifier for Groups of Physicians**

| NQF Number | Measure Title | Measure Steward | Domain of Care |
|---|---|---|---|
| N/A | **1. Composite of Acute Prevention Quality Indicators** | N/A | Care Coordination |
| 0279 | **Bacterial Pneumonia**<br>The number of admissions for bacterial pneumonia per 100,000 population. | AHRQ | |
| 0281 | **UTI**<br>The number of discharges for urinary tract infection per 100,000 population Age 18 Years and Older in a one year time period | AHRQ | |
| 0280 | **Dehydration**<br>The number of admissions for dehydration per 100,000 population. | AHRQ | |
| N/A | **2. Composite of Chronic Prevention Quality Indicators** | N/A | Care Coordination |
| | **Diabetes Composite** | | |
| 0638 | **Uncontrolled diabetes**<br>The number of discharges for uncontrolled diabetes per 100,000 population | AHRQ | |

[15] N Engl J Med 2009; 360:1418-1428

| | | | |
|---|---|---|---|
| | Age 18 Years and Older in a one year time period. | | |
| 0272 | **Short Term Diabetes complications**<br>The number of discharges for diabetes short-term complications per 100,000 Age 18 Years and Older population in a one year period. | AHRQ | |
| 0274 | **Long term diabetes complications**<br>The number of discharges for long-term diabetes complications per 100,000 population Age 18 Years and in a one year time period. | AHRQ | |
| 0285 | **Lower extremity amputation for diabetes**<br>The number of discharges for lower-extremity amputation among patients with diabetes per 100,000 population Age 18 Years in a one year time period. | AHRQ | |
| 0275 | **COPD**<br>The number of admissions for chronic obstructive pulmonary disease (COPD) per 100,000 population. | AHRQ | |
| 0277 | **Heart Failure**<br>Percent of the population with admissions for CHF. | AHRQ | |
| N/A | **3. All Cause Readmission**<br>The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned. | CMS | Care Coordination |
| N/A | **4. 30 Day Post Discharge Visit**<br>The rate of provider visits within 30 days of discharge from an acute care hospital per 1,000 discharges among eligible beneficiaries assigned. | CMS | Care Coordination |

We also note that we are making plans to seek National Quality Forum endorsement for these four measures as required by section 1848(p)(2)(B)(ii) of the Act. We seek comment on our proposals to use these four measures in the value-based payment modifier for all groups of physicians with 25 or more eligible professionals.

At this time we are not making proposals regarding how to assess community-level performance and how such assessments could be included in the value-based payment modifier for groups of physicians. We seek comment, however, on whether measurement and adjustment at the community level would further our objectives to encourage and reward physicians and groups of physicians for furnishing high-quality, efficient, patient-centered clinical care.

d. Proposed Cost Measures

Section 1848(p)(3) of the Act requires us to evaluate costs, to the extent practicable, based on a composite of appropriate measures of costs. In the CY 2012 PFS final rule with comment period (76 FR 73434), we finalized use of total per capita cost measures and per capita costs measures for beneficiaries with four specific chronic conditions (chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes) for the value-based

payment modifier. Total per capita costs include payments under both Part A and Part B. Total per capita costs do not include Medicare payments under Part D for drug expenses. We propose to use at least a 60-day run out with a completion factor from our Office of the Actuary (for example, claims paid through March 1 of the year following December 31, the close of the performance period) to calculate the total per capita cost measures. We seek comment on this proposal.

We used these five measures in the 2010 Physician Feedback reports for individual physicians and physician groups; they also will be included in the 2011 Physician Feedback reports that we expect to disseminate later in 2012. We propose to continue to use these five measures to calculate the cost composite for the value-based payment modifier. We also are developing plans to submit these per capita cost measures for National Quality Forum endorsement.

Several recipients of the 2010 Physician Feedback reports objected to being "held responsible" for total per capita costs of the beneficiaries that they treated, because they could not affect the other costs incurred by the patient. In our view, the total per capita cost measure is just one metric used to assess the costs of care. It has no impact until we use it to make comparisons among physicians and groups of physicians. In other words, it is not the measure itself (because it reflects the total cost of care beneficiaries received), but how we use it to assess performance that matters. As described more fully in the composite scoring methodology proposals below, we propose to make cost comparisons among groups of physicians using a similar beneficiary attribution methodology such that we make "apples to apples" comparisons. We believe that this would be an appropriate approach to using the total per capita cost measure in the value-based payment modifier. We seek comment on these proposals.

(1) Proposed Payment Standardization Methodology for Cost Measures

Section 1848(p)(3) of the Act requires that "…costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary (such as the composite measure under the methodology established under section 1848(n)(9)(C)(iii)) that eliminate the effect of geographic adjustments in payment rates (as described in subsection (e))…" In layman's terms, this directive requires us to standardize Medicare payments to ensure fair comparisons across geographic areas.

Payment standardization removes local or regional price differences that may cause cost variation a physician cannot influence through practicing efficient care. In Medicare, an effective payment standardization methodology would exclude Medicare geographic adjustment factors such as the geographic practice cost index (GPCI) and the hospital wage index so that, for example, per capita costs for beneficiaries in Boston, Massachusetts can be compared to those of beneficiaries in Lincoln, Nebraska. Payment standardization, therefore, allows fair comparisons of resource use costs for physicians to those of peers who may practice in locations or facilities where Medicare payments are higher or lower.

We have developed a detailed Medicare payment standardization methodology that excludes such geographic payment rate differences. We developed the methodology with substantial stakeholder input, and we update it annually to incorporate any payment system changes. More details of the CMS payment standardization methodology that we are proposing can be found at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.

We have used this standardization approach, for example, in feedback reports we provide to hospitals related to the Medicare Spending per Beneficiary measure. The CMS payment standardization methodology includes a number of payment adjustments across the spectrum of

fee-for-service Medicare. For example, the methodology eliminates adjustments made to national payment amounts that reflect PE and regional labor cost differences (measured by the GPCI and hospital wage index); substitutes a national amount when services are paid using a state fee schedule; eliminates supplemental payments to hospitals that treat a high share of poor and uninsured patients (that is, Medicare disproportionate share hospital (DSH) payments) or that receive indirect graduate medical education (IME) payments; removes incremental payments for community hospitals and Medicare-dependent hospitals above their base payments; and eliminates certain rural add-on payments for inpatient psychiatric hospitals and inpatient rehabilitation facilities. Outlier payments are treated as they would be if payments were not standardized, but they are adjusted to reflect wage differences.

The CMS payment standardization methodology also eliminates the effect of incentive payments under the PFS for physicians that furnish services in rural areas and other underserved communities such that they are not disadvantaged in the value-based payment modifier. For example, section 1833(m) of the Act provides incentive payments for physicians who furnish medical care services in geographic areas that are designated as primary medical care Health Professional Shortage Areas (HPSAs) under section 332 (a)(1)(A) of the Public Health Service (PHS) Act. The CMS standardization methodology does not include these incentive payments in standardized Part B costs so that physicians that furnish services in these areas are not disadvantaged in the value-based payment modifier. We believe that by doing so we are complying with the requirement in Section 1848(p)(6) to "take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities when applying the value-based payment modifier."

We standardized the cost measures in the 2010 Physician Feedback reports to allow fair comparisons of costs across physicians. However, we note that the methodology used in the

2010 Physician Feedback reports differs from the methodology that we are proposing for the value-based payment modifier. Although that methodology achieved the same goal of ensuring fair comparisons, the standardization techniques used for the 2010 reports were performed at the regional level (because the reports focused on providers in four states) and used an averaging approach. Thus many of the national adjustments that we have proposed in this rule were not applicable to the 2010 Physician Feedback reports. In the 2011 Physician Feedback reports that we expect to disseminate later in 2012, we will use the national payment standardization methodology currently used to standardize payments in hospital feedback reports for the Medicare Spending per Beneficiary measure. We propose to use that same methodology to standardize cost measures for purposes of the value-based payment modifier. We believe that this approach to payment standardization allows us to standardize payments nationally and to use a consistent approach across multiple programs and CMS initiatives. We seek comments on this proposal.

(2) Proposed Risk Adjustment Methodology for Cost Measures

Section 1848(p)(3) of the Act requires that costs be adjusted to "…take into account risk factors[,] such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions) and other factors determined appropriate by the Secretary."

Risk adjustment accounts for differences in patient characteristics not directly related to patient care, but that may increase or decrease the costs of care. In the Physician Feedback reports, after standardizing per capita costs for geographic factors, we also adjusted them 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. Thus, for individual physicians or physician groups who have a higher than average proportion of patients with serious medical conditions or other higher-cost risk factors, risk adjusted per capita costs are lower than the unadjusted costs, because costs of higher-risk patients are adjusted downward. Similarly, for individual physicians or physician groups who treated comparatively lower-risk patients, risk adjusted per capita costs were higher than unadjusted costs, because costs for lower-risk patients were adjusted upwards.

In the Physician Feedback program, we applied a risk adjustment methodology to account for patient differences in per capita costs that were due to patient demographics such as age and gender, socioeconomic factors such as Medicaid dual eligible status, and prior health conditions that can affect a beneficiary's costs, regardless of the efficiency of the care provided. This risk adjustment methodology uses the CMS' Hierarchical Condition Categories (HCC) model, which incorporates beneficiary characteristics and prior year diagnoses to predict relative Medicare Part A and Part B payments. This model was originally developed under contract to CMS by researchers at Boston University and Research Triangle Institute (RTI) with clinical input from Harvard Medical School physicians based on an analysis of Medicare FFS beneficiaries diagnoses and expenditures. The model is updated every year to incorporate new diagnosis codes and is recalibrated regularly to reflect more recent diagnosis and expenditure data.

The HCC model assigns prior year ICD-9-CM diagnosis codes (each with similar disease characteristics and costs) to 70 generally high-cost clinical conditions to capture medical condition risk. The HCC risk scores also incorporate patient age, gender, reason for Medicare eligibility (age or disability), and Medicaid eligibility status, which is in part a proxy for socioeconomic status and reflects the greater resources typically used by beneficiaries eligible for both Medicare and Medicaid. The risk adjustment model also includes the beneficiary's end

stage renal disease (ESRD) status. More information about the risk adjustment model is on the CMS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/122111_Slide_Presentation.pdf.

We have examined the impacts of applying the above risk adjustment methodology for physicians included at the group and individual level in the 2010 Physician Feedback reports and believe the approach provides a reasonable method to adjust per capita costs based on beneficiary characteristics. The results show that the risk adjustment methodology, in the aggregate, compresses the range of per capita costs substantially and that a group of physicians' total per capita cost measures can experience substantial adjustment based upon the risk profile of the beneficiary population. For groups of physicians, the risk adjustment methodology had the effect of reducing the absolute difference between the groups with the lowest per capita cost and the highest total per capita cost by 55.7 percent. In particular, the lowest third of the groups were increased by an average of 6.2 percent and the most expensive third were lowered by 10.4 percent. The middle third, on average, were lowered by 0.1 percent. The range of adjustments was between -10.3 percent and +8.2 percent. We found similar results at the individual level.

We propose to use the same risk adjustment model for risk adjusting total per capita costs and the total per capita costs for beneficiaries with four chronic diseases (coronary artery disease, COPD, diabetes, and heart failure) as we have used for the group and individual 2010 Physician Feedback reports. We seek public comment on applying the same risk adjustment approach to the value-based payment modifier as with the Physician Feedback reports.

(3) Episode-based Cost Measures

Section 1848(n)(9)(A)(ii) of the Act as added by section 3003 of the Affordable Care Act, required CMS to develop a Medicare episode grouper by January 1, 2012. Four contractors submitted prototype episode groupers to CMS in September 2011, and, after evaluating the

prototypes, we selected one to develop its prototype episode grouper into a comprehensive Medicare episode grouper. This process will entail additional technical and analytical development, as well as testing of the more fully developed episode grouping product. Initially the episode grouper will focus on selected chronic conditions and acute events. As development of the selected episode grouper continues, we expect to see the number of conditions increase. We plan to use the episode grouper in future Physician Feedback reports in order to test and gain stakeholder input into the development of the episodes of care.

Although the statute does not require the use of the episode-based cost measures for the value-based payment modifier, it requires that we use such cost measures in the Physician Feedback reports. We plan to include episode-based cost measures for several conditions in the Physician Feedback reports beginning in 2013 (based on 2012 data). Interested parties that commented on the CY 2012 PFS final rule with comment period (76 FR 73434) recommended that we use episode-based cost measures in the value-based payment modifier, rather than total per capita costs, because episode-based costs are used in many private sector pay-for-performance programs and directly reflect care provided by physicians. We anticipate providing episode-based cost measures in the Physician Feedback reports before proposing them for the value-based payment modifier in future rulemaking.

e. Attribution of Quality and Cost Measures

Calculation of administrative claims-based quality and cost measure performance rates requires us to attribute Medicare beneficiaries to groups of physicians. For example, for the PQRS administrative claims-based reporting option, we must attribute beneficiaries to groups of physicians (as identified by a single TIN) so that we are able to calculate the relevant quality measure and cost measure performance rates. Likewise, we must attribute beneficiaries to groups of physicians that submit data on quality measures under the PQRS GPRO in order to

calculate the cost measure performance rates. In the 2010 Physician Feedback reports, we used two different attribution methodologies: one method for individual physicians ("degree of involvement method") and another method for groups of physicians ("plurality of care method"). This section discusses our proposals for using these attribution methods to calculate the quality and cost measures for the value-based payment modifier. We note that the attribution methods do not impact beneficiaries' choice of providers.

We used the plurality of care method to attribute beneficiaries in the 2010 Physician Feedback reports provided to the group practices using the PQRS GPRO web-interface. In this method, we attributed Medicare FFS beneficiaries to the group practice that billed a larger share of office and other outpatient Evaluation and Management (E/M) services (based on dollars) than any other group of physician practice (that is, the plurality). In addition, beneficiaries had to have at least two E/M services at the group of physicians. We used this attributed population to identify a sample of beneficiaries eligible for the quality measures reported via the PQRS GPRO web-interface. We also calculated the per capita cost measures based on this attributed population.

In the discussion above regarding beneficiary attribution for groups of physicians choosing to report quality measures through the PQRS GPRO web-interface, we are seeking comment on the continued use of the "plurality of care" attribution methodology or to use the Medicare Shared Savings Program attribution methodology for 2013 and beyond. The Medicare Shared Savings Program attribution methodology is described at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Statutes_Regulations_Guidance.html. For purposes of program alignment, we propose to use the same attribution methodology that we finalize for the PQRS GPRO web-interface to attribute beneficiaries to groups of physicians for purposes of the value-

based payment modifier. This proposal means that we would calculate the per capita cost measures based on the same attributed beneficiary population as we use for determining the quality measures for the group of physicians that report PQRS quality data through: PQRS GPRO using the web-interface, claims, registries, or EHRs; or PQRS administrative claims-based option.

We are concerned, however, that such an attribution methodology may be too restrictive because it relies solely on office (E/M) visit codes and it could fail to attribute beneficiaries whom the group practices would identify as their beneficiaries. This situation may occur, for example, with single specialty groups such as radiologists or anesthesiologists that do not submit claims that use E/M codes. For these reasons, we seek comment on whether to use an alternative approach (such as the "degree of involvement" method that is discussed next) for all groups of physicians except those reporting quality measures using the PQRS GPRO web-interface.

We used the "degree of involvement" method to attribute beneficiaries for cost purposes to individual physicians in the CY 2010 Physician Feedback reports, which we produced for physicians (23,730 physicians in total) in four states: Iowa; Kansas; Missouri; and Nebraska. Under this attribution method, we classified the patients for which a physician submitted at least one Medicare FFS Part B claim into three categories (directed, influenced, and contributed) based on the amount of physician involvement with the patient:[16]

- For directed patients, the physician billed for 35 percent or more of the patient's office or other outpatient evaluation and management (E&M) visits.
- For influenced patients, the physician billed for fewer than 35 percent of the patient's outpatient E&M visits but for 20 percent or more of the patient's total professional costs.
- For contributed patients, the physician billed for fewer than 35 percent of the patient's

[16] CMS, "Detailed Methodology for Individual Physician Reports" (2012), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/QRURs_for_Individual_Physicians.pdf

outpatient E&M visits and for less than 20 percent of the patient's total professional costs.

The result of this methodology is that all of the beneficiaries for which a physician submitted Medicare Part B claims are attributed to the physician, but the beneficiaries are classified according to the degree of physician involvement with the beneficiary. We then calculated per capita cost measures for the beneficiaries within each of these three classifications. In addition, a beneficiary can be attributed to more than one physician (and in different categories) if the beneficiary received services from more than one physician.

Based on the CY 2010 reports, physicians that "directed" care billed, on average, approximately three E/M visits with the patient, which represented over 64 percent of all E/M services furnished by the physicians treating the beneficiary. Although the directed attribution rule permits two physicians to be attributed to the same beneficiary (because only two physicians could each have greater than 35 percent of the beneficiaries E/M visits), in practice that rarely happened as a physician that directed care of a beneficiary had the substantial majority of E/M visits, that accounted for 31 percent of costs among all physicians treating the beneficiary. These observations indicate the physician had substantial control over the patient's care. In addition to primary care specialties, the other specialties with the greatest percentage of physicians directing care were rheumatology and oncology.

Physicians that "influenced" care had, on average, one E/M visit with the beneficiary, but also had slightly over one-third of the beneficiaries' total Part B costs. Although the average number of E/M visits was low, the physician, on average, billed for one procedure during the year and this procedure was the most expensive one for the patient. This share of Part B costs was greater than physicians that directed or contributed to a beneficiary's care. Although the influenced attribution rule permits up to five physicians to influence care (because five physicians could each bill 20 percent of total Part B costs), this rarely happened as a physician

that influenced care of a beneficiary had, on average, approximately 84 percent of total Part B costs compared to other physicians that could have influenced care. Medical specialists and surgeons, including ophthalmology, orthopedic surgery, plastic and reconstructive surgery had the greatest percent of beneficiaries for which they influenced care.

Physicians that "contributed" to care had, on average, less than one E/M visit per year with the beneficiary and billed for less than, on average, 20 percent of average beneficiaries' total professional costs, thus indicating that the beneficiary received care from many providers. On average, at least five physicians contributed to a beneficiary's care (not including those that directed or influenced that care).

We calculated average total per capita cost measures for physicians by attribution rule and these costs are shown in Table 67. Not surprisingly, total per capita costs for directed and influenced beneficiaries were about 50 percent of the total per capita costs of physicians with contributed beneficiaries. The costs in Table 67 show that beneficiaries that receive care from multiple physicians, have substantially higher per capita costs. In addition, approximately 20 percent of Medicare beneficiaries covered by the 2010 Physician Feedback reports had contributed care in which physicians only contributed to it. In other words, the care furnished was neither "directed" nor "influenced" by a physician.

**TABLE 67: Average Per Capita Costs by Attribution Rule for Physicians in Iowa, Kansas, Nebraska, and Missouri**

| Attribution Rule | Average Total Per Capita Cost |
|---|---|
| All physicians | $18,831 |
| Physicians with Directed Beneficiaries | $10,719 |
| Physicians with Influenced Beneficiaries | $9,407 |
| Physicians with Contributed Beneficiaries | $20,243 |

We believe the value-based payment modifier should address not only the care for

beneficiaries that a physician may "direct" or "influence," but also play a role in encouraging more efficient, not just more, care for beneficiaries. We believe that any attribution rule should consider the "contributed" beneficiaries, especially those beneficiaries that are neither directed nor influenced by other physicians, because the care of these beneficiaries is where the greatest potential for improved care and coordination reside.

As explained more below, we seek comment on whether to attribute two populations of beneficiaries to groups of physicians using (1) a combination of the directed and influenced rules and (2) the contributed rule. If we were to finalize this attribution methodology, we would calculate a separate per capita cost measures for each patient population. For example, we would calculate one total per capita cost measure for the groups of physicians' "directed and influenced" beneficiaries and a second total per capita cost measure for the groups' "contributed" beneficiaries. (In the value-based payment modifier scoring methodology section below, we explain our proposals for how to score and weight these measures to ensure fair comparisons among groups of physicians).

First, we would attribute beneficiaries to a group of physicians that billed for 35 percent or more of the patient's office or other outpatient (E/M) visits or at least 20 percent or more of the beneficiary's total professional costs. This proposal combines the "directed" and "influenced" methods discussed above. Combining "directed" and "influenced" beneficiaries into one attributed patient population is reasonable because groups of physicians that care for these beneficiaries treat them, on average, more than any other physician or are responsible for a large percentage of professional costs. Combining the "directed" and "influenced" rules attributes beneficiaries to the group of physicians over which they have substantial control of resource utilization.

Second, we would attribute a second and separate patient population to the group of physicians which would consist of the remaining beneficiaries to whom a group of physicians provided service but who were not attributed in the first patient population (for example, beneficiaries for which the group of physicians did not bill for 35 percent of more of E/M visits and for less than 20 percent of professional costs). This rule corresponds to the "contributed" category discussed above. We believe that attributing a second patient population to groups of physicians ensures accountability for all beneficiaries to whom a group of physicians furnishes services. We seek comment on whether to use the "degree of involvement" attribution method for all groups of physicians that submit data on PQRS quality measures through PQRS GPRO using claims, registries, and EHRs, and through the PQRS administrative claims-based option.

f. Proposed Composite Scores for the Value-Based Payment Modifier

Section 1848(p)(2) of the Act requires that quality of care be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished. Likewise, section 1848(p)(3) of the Act requires that cost measures used in the value-based payment modifier be evaluated, to the extent practicable, based on a composite of appropriate measures of costs. This section discusses our proposals for constructing the quality of care and cost composites.

(1) Proposed Quality of Care and Cost Domains

In many of our value-based purchasing programs such as Hospital Value-Based Purchasing and the Medicare Shared Savings Program, we selected and classified measures into quality domains that reflect important national objectives for quality assessment and improvement. We believe it is important to align the quality measures used in the value-based payment modifier with the national priorities established in the National Quality Strategy. The National Quality Strategy outlined six priorities including:

- Make care safer by reducing harm caused in the delivery of care (patient safety).

- Ensure that care engages each person and family as partners (patient experience).
- Promote effective communication and coordination of care (care coordination).
- Promote the most effective prevention and treatment practices for leading causes of mortality (clinical care).
- Work with communities to promote wide use of best practice to enable healthy living (population/community health).
- Make quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models (efficiency).[17]

We propose to classify each of the quality measures that we proposed for the value-based payment modifier into one of these six domains. We propose to weight each domain equally to form a quality of care composite. We believe this is a straightforward approach that recognizes the importance of each domain. Within each domain, we propose to weight each measure equally so that groups of physicians have equal incentives to improve care delivery on all measures. To the extent that a domain does not contain quality measures, the remaining domains would be equally weighted to form the quality of care composite. For example, if three domains contain quality information, each domain would be weighted at 33.3 percent to form the quality composite.

In terms of the cost composite, we finalized in the CY 2012 PFS final rule (76 FR 73434) total per capita costs (Parts A and B) and total per capita costs for beneficiaries with four chronic diseases (diabetes, CAD, COPD, heart failure). We propose to group these five per capita cost measures into two separate domains: total overall cost (one measure) and total costs for beneficiaries with specific conditions (four measures). A separate domain for costs for beneficiaries with specific conditions highlights our desire to incentivize efficient care for

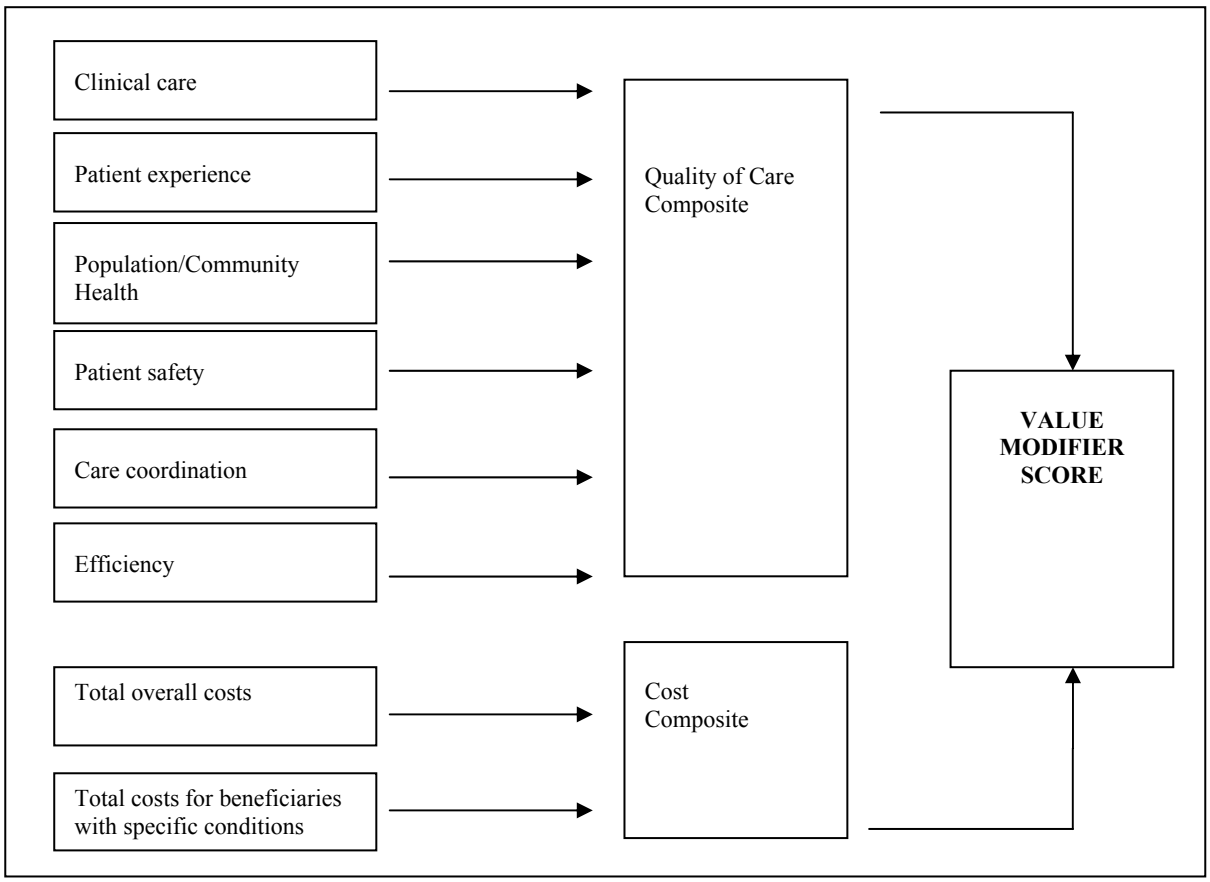
[17] National Quality Strategy, http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.

beneficiaries with these conditions.

Similar to the quality of care composite, we propose to weight each cost domain equally to form the cost composite and within the cost domains we propose to weight each measure equally. In those instances in which we cannot calculate a particular cost measure, for example due to too few cases, we propose to weight the remaining cost measures in the domain equally.

If we were to attribute two patient populations to each group of physicians as discussed above regarding the "degree of involvement" attribution methodology, we propose to weight the measures in each population based on the group of physicians' allowed charges for beneficiaries attributed to each population so that the cost composite accurately reflects the cost of care furnished. We seek comment on these proposals. Table 68 graphically depicts these proposals for the quality of care and cost composites and how they relate to the value-based payment modifier.

**TABLE 68: Relationship between Quality of Care and Cost Composites and the Value-Based Payment Modifier**




(2) Proposed Value-Based Payment Modifier Scoring Methods

We adopted different methods to score quality and cost measures in our value-based purchasing programs with each scoring methodology tailored to further the program's purpose. For example, in the Medicare Shared Savings Program, we finalized a point system scoring methodology that assesses performance against established Medicare program benchmarks for each quality measure. In the hospital-value based purchasing program, we used a point system methodology that considered both a hospital's achievement and improvement from a baseline performance period. We then translated these points using a linear exchange function to develop a unique payment modifier for each hospital.

For the value-based payment modifier, we believe the composite scoring methodology

should keep intact the underlying distribution of performance rates so that the composite scores distinguish clearly between high and low performance. Groups of physicians also should easily be able to understand how performance on a quality or cost measure can affect their composite score, and hence their payment. We also believe that the composite scoring methodology should be used at all performance assessment levels (individual physician, group of physicians, hospital). Thus, because we are proposing to provide flexibility to groups of physicians as to the quality measures they report, the scoring methodology needs to be able to compare "apples to apples."

Therefore, we propose a scoring approach that focuses on how the group of physicians' performance differs from the benchmark on a measure-by-measure basis. For each quality and cost measure, we propose to divide the difference between a group of physicians' performance rate and the benchmark by the measure's standard deviation. The benchmarks, as further described below, are the national means of the quality or cost measure. This step produces a score for each measure that is expressed in standardized units. As discussed above, we propose to weight each measure's standardized score equally with other measures in the domain to obtain the domain standardized score. We propose to weight the domain scores equally to form the quality of care and cost composites. We seek comment on this proposal.

We believe that this proposal achieves our policy objective to distinguish clearly between high and low performance and to allow us to create composites of quality of care for groups of physicians that report different quality measures. We also note that this approach is used in several private sector physician profiling efforts.[18]

Table 69 illustrates how we would score three hypothetical quality measures in the same quality domain under our proposal. A standardized score of zero means that performance is at

[18] See e.g., Tufts Health Plan, "How Does Tufts Health Plan Tier Its Doctors" available at http://www.tuftshealthplan.com/members/members.php?sec=how_your_plan_works&content=your_choice&rightnav=your_choice_nav&WT.mc_id=members_leftnav_hypw_yourchoice&WT.mc_ev=click

the national mean. Higher standardized scores (for example, 2.98) mean that performance is better than the national mean. Likewise, a large negative score means that performance is much lower than the national mean. In the example shown in Table 69, the quality domain score would be 0.79 (the average of the three quality measures' standardized units) meaning the group of physicians scored slightly better than average in this quality domain. We would use the same method for the quality measures in the other domains that a group of physicians reported.

**TABLE 69: Example of Standardized Scores in one Quality Domain**

| | Group of Physicians' Performance Rate | Benchmark (National Mean) | Standard Deviation | **Standardized Unit** |
|---|---|---|---|---|
| **Quality Measures** | | | | |
| Measure 1 | 95.0 | 93.5 | 3.3 | **0.47** |
| Measure 2 | 71.4 | 86.3 | 13.9 | **-1.07** |
| Measure 3 | 100.0 | 60.6 | 13.2 | **2.98** |
| **Quality Domain Score** | | | | **0.79** |

(3) Proposed Benchmarks and Peer Groups for Quality Measures

We propose that the benchmark for each quality measure be the national mean of each measure's performance rate during the performance period. We propose to unify the calculation of the benchmark by weighting the performance rate of each physician and group of physicians submitting data on the quality measure by the number of cases used to calculate the performance rate. Alternatively, we could weight each quality measure reported by groups of physicians by the number of physicians in the group. We seek not to bias how physicians choose to report quality measures (that is, at the group or individual level) by establishing different benchmarks for the same quality measures. Moreover, we believe beneficiaries are entitled to high quality care, regardless of whether a group of physicians or an individual physician furnishes it.

In addition, we propose that the benchmarks for quality measures in the PQRS

administrative claims-based reporting option be the national mean of each quality measure's performance rate calculated at the TIN level. We propose to calculate the national mean by including the all TINs of groups of physicians with 25 or more eligible professionals. We propose to weight the TIN's performance rate by the number of cases used to calculate the quality measure.

To help groups of physicians understand how their quality measure performance affects their quality of care composite score, we propose to publish the previous years' performance rates (and standardized scores) on each quality measure. By doing so, groups of physicians will be better informed on how their performance may affect their payment in the coming year. We note, for example, that "topped out" quality measures are unlikely to have significantly higher or lower standardized scores for each measure because performance is clustered around the mean, and this scoring method seeks to differentiate performance from the mean. We seek comment on these proposals.

(4) Proposed Benchmarks and Peer Groups for Cost Measures

To ensure fair cost comparisons that identify groups of physicians that are outliers (both high and low), we believe the same methodology should be used to attribute beneficiaries to the groups of physicians and to the groups of physicians in the peer group. We seek to compare like groups of physicians that use the same cost attribution methodology to ensure we are making "apples to apples" comparisons among groups of physicians. As discussed above, there are two ways to attribute beneficiaries to groups of physicians ("plurality of care" and "degree of involvement"). We have proposed to use the "plurality of care" method for groups of physicians, regardless of whether they report data on PQRS quality measures using the GPRO web-interface, claims, registries, or EHRs; or the PQRS administrative claims-based option.

Thus, we propose that the peer group for the cost measures include all other groups of physicians for which we use the "plurality of care" to attribute beneficiaries.

We seek comment on how the cost measure peer groups would change if we adopt the "degree of involvement" methodology for groups of physicians other than groups of physicians using the PQRS GPRO web-interface to submit data on quality measures.

Alternatively, we seek comment on establishing cost benchmarks on a quality measure-by-quality measure basis. Under this alternative approach, we would set the benchmark as the mean per capita cost of the physicians or groups of physicians that reported the quality measure – whether it was reported by a group of physicians or at the individual physician level. This approach encourages groups of physicians to select to report quality measures that reflect their practice patterns and patient populations more accurately. We seek comment on whether we should adopt this approach.

We also note that although we are not proposing in this rule to use episode-based costs, the scoring methodology that we have proposed can readily be used to identify high and low performers relative to a national benchmark for episodes of care. For example, we could develop an episode cost profile for a typical beneficiary with macular degeneration. We could then use the proposed scoring methodology to identify groups of physicians that have high and low episode costs relative to the benchmark. In addition, if we were to use such episode-based cost measures, we could use attribution methods that seek to stratify beneficiaries by relevant condition-specific characteristics to ensure fair and accurate peer group comparisons among physicians. We seek comment on our plans to use this approach in the future.

(5) Proposed Reliability Standard

We believe it is crucial that the value-based payment modifier be based on quality of care and cost composites that reliably measure performance. Statistical reliability depends on

performance variation for a measure across physicians ("signal"), the random variation in performance for a measure within a physician's payment of attributed beneficiaries ("noise"), and the number of beneficiaries attributed to the physician. In other words, reliability is defined as the extent to which variation in the measure's performance rate is due to variation in the quality (or cost) furnished by the physicians (or group of physicians) rather than random variation due to the sample of cases observed. Reliability is important so that we can confidently distinguish the performance of one physician (or group of physicians) from another.[19] 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 differences in performance across physicians (or groups of physicians). Generally, reliabilities in the 0.40-0.70 range are often considered moderate and values greater than 0.70 high.

Therefore, we propose to establish a minimum number of cases in order for a quality or cost measure to be included in the quality of care or cost composite. To the extent that a group of physicians fails to meet the minimum number of cases for a particular measure, the measure would not be counted and the remaining measures in the domain would be given equal weight. To the extent that we cannot develop either a reliable quality of care composite or cost composite because we do not have reliable domain information, we would not calculate a value-based payment modifier and payment would not be affected. We recognize that a trade-off exists between developing a program that will eventually cover all physicians and groups of physicians and providing statistically reliable performance results. In this instance, as we increase the reliability threshold by requiring a higher minimum case size threshold, the number of physicians and groups of physicians for which we can develop a reliable quality of care or cost composite decreases. Based on an analysis of the individual CY 2010 Physician Feedback reports and on

[19] John L. Adams, "The Reliability of Provider Profiling, A Tutorial," Rand Corporation (2009).

recent literature, we propose a minimum case size of 20 for both quality and cost measures to ensure high statistical reliability.[20] This proposal means that if a group of physicians does not have 20 or more beneficiaries eligible for a particular measure, that particular measure would not be included in the calculation of the value-based payment modifier.

Our reliability analysis of the quality and cost measures in the 2010 individual Physician Feedback reports informs our minimum case size proposal. The average reliability of the total per capita cost measure assessed at the individual level for physicians in all specialties was high (greater than .70) when the minimum case size was 20 or more. There was a slight increase in average reliability by increasing minimum case size to 30 cases. Increasing the minimum case size from 20 to 30, however, decreases the number of physicians for which we can calculate a reliable cost measure for physicians. The decrease in the number of physicians is small for some specialties (for example, internal medicine, family practice) but is much greater for other specialties (for example, thoracic surgery, allergy/immunology).

Reliability was high for nine of the 15 administrative claims based quality measures that we are proposing for purposes of the value-based payment modifier for the PQRS administrative claims-based reporting option when the minimum case size was 20 or greater. Average reliability increases slightly by increasing case size to 30, but the number of physicians decreases, on average, by 30 percent of eligible physicians. We anticipate that statistical reliability of the quality and cost measures will increase when we assess physicians at the TIN level rather than NPI level, because, on average, a TIN will be attributed more beneficiaries than an NPI. We seek comment on these proposals.

g. Proposed Payment Adjustment Amount

[20] Robert L. Houchens, "The Reliability of Physician Cost Profiling in Medicare," (Aug. 2010) (Describing how for most physician specialties, Medicare physician cost profile scores are substantially more reliability than those derived from commercial settings,)

Section 1848(p) of the Act does not specify the amount of physician 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 payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians due to high performance and decrease for others due to 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 making proposals about the amount of Medicare payment made under the PFS at risk for the value-based payment modifier, we considered that there are two other payment adjustments affecting physicians' Medicare payment in 2015 that could further decrease physician payments in 2016. Specifically, under PQRS, a physician who does not satisfactorily submit data on quality measures during the applicable reporting period in 2013 have their fee schedule amount reduced by 1.5 percent for service furnished in 2015. This PQRS downward payment adjustment to the fee schedule will increase to 2 percent in 2016 (and thereafter) based on reporting periods that fall in CY 2014 (and thereafter, reporting period or periods that fall two years prior to the year in which the PQRS payment adjustment is assessed). However, as noted previously in this preamble, individual physicians and groups of physicians that satisfactorily submit data on PQRS quality measures via any of the reporting methods proposed for the 2015 and 2016 PQRS payment adjustment would avoid the PQRS downward payment adjustment. The second payment adjustment is for physicians that are not meaningful EHR users. Section 1848(a)(7) of the Act provides for a downward payment adjustment of 1 percent in 2015 (based on performance in 2013), 2 percent in 2016 (performance in 2014), and 3 percent in 2017 (performance in 2015). We note that the adjustment in 2015 for not being a meaningful EHR

user is increased by 1 percentage point (to -2 percent) if the physician was subject to the eRx Incentive Program payment adjustment for 2014.

To balance our goals of beginning the implementation of the value modifier consistent with the legislative requirements and to give us and the physician community experience in its operation, we propose to separate groups of physicians with 25 or more eligible professionals into two categories.

For those groups of physicians that have met the criteria for satisfactory reporting established for the value-based payment modifier and request that their value-based payment modifier be calculated using a quality-tiering approach, we propose that the maximum payment adjustment be -1.0 percent for poor performance (Table 70 displays the different downward payment adjustments depending upon a group of physicians' quality and cost tiers). We recognize that 2015 is the initial year for the value-based modifier and, thus, we are providing for a very modest adjustment for the program's initial years. A payment adjustment of -1.0 percent means that groups of physicians would receive 99.0 percent of the PFS payment amount for the service involved. Due to the BN requirement, we are not proposing the exact amount of the upward payment adjustments for high performance under the value-based payment modifier because the upward payment adjustments (in the aggregate) will have to balance the downward payment adjustments in order to achieve BN. Thus, we propose to determine the projected aggregate amount of downward payment adjustments and then calculate the upward payment adjustment factor based on the amount of the projected aggregate upward payment adjustments. Our proposals regarding the payment modifier scoring models in the next section explain how we proposed to calculate upward adjustments for high performance.

For groups of physicians with 25 or more eligible professional that have not met the criteria for satisfactory reporting established for the value-based payment modifier (including

those groups that have not participated in any of the PQRS reporting mechanisms), we propose to set their value-based payment modifier at -1.0 percent. We arrived at our proposal for a -1.0 percent downward adjustment using the following rationale. Section 1848(p) of the Act requires us to differentiate payment based on a comparison of quality of care furnished compared to cost. Because we do not have performance rates on which to assess the quality of care furnished by these groups, we can differentiate payment based on costs only. A cost-only comparison would set a lower downward adjustment for low-cost groups than for high-cost groups. Due to the fact that the value-based payment modifier is just starting in 2015, we do not wish to apply a greater downward payment adjustment for non-satisfactory reporters than we are proposing for the low quality/high cost groups that request that their value-based payment modifier be calculated using a quality-tiering approach. Thus, we propose to equalize the downward payment adjustment across these groups of physicians, despite the fact that they may have different costs. We seek comment on this approach.

h. Proposed Value-Based Payment Modifier Scoring Methodology

Section 1848(p)(1) of the Act requires the Secretary to establish a payment modifier that provides for differential payment to a physician or group of physicians under the fee schedule based upon the quality of care furnished compared to cost during a performance period. As noted previously, the statute requires that quality of care furnished and cost shall be evaluated, to the extent practicable, based on composites of quality of care furnished and cost. This section discusses our proposals for comparing the quality of care furnished to cost for those groups of physicians that request their value-based payment modifier be calculated using a quality-tiering approach.

In making our proposals, we developed two models that compare the quality of care furnished to costs: a quality tier model and a total performance score model. We propose the

quality-tiering model for the value-based payment modifier, but we seek comment on the total performance score model. We also note that the literature on physician pay-for-performance includes other models, such as one based on an efficient frontier, that we are not proposing here.[21] We seek comment on these proposals.

(1) Quality-Tiering Model

The quality-tiering model compares the quality of care composite with the cost composite to determine the value-based payment modifier. To make this comparison, we propose to classify the quality of care composites scores into high, average, and low quality of care categories based on whether they are statistically above, not different from, or below the mean quality composite score. We seek to ensure that those groups of physicians classified as high or low performers have performance that is meaningfully different from average performance (to be sure that no group of physicians is disadvantaged for performance only slightly different from the benchmark) and is precisely measured (to ensure that no group of physicians is disadvantaged by an inaccurate performance assessment). We propose to assess meaningful differences as those performance scores that are at least one standard deviation from the mean. We propose to assess precision by requiring a group of physicians' score to be statistically different from the mean at the 5.0 percent level of significance. We seek comment on these proposals and on whether we should only examine meaningful differences that are at least two or three standard deviations away from the mean. We also seek comment on whether to define the high and low categories of the quality composites as a fixed percentage (for example, 2.5 percent) of the number of groups of physicians or of the amount of payments under the PFS. Such an approach would minimize the number of group of physicians subject to payment adjustments.

[21] David Knutson, et al, "Alternative Approaches to Measuring Physician Resource Use," Second Interim Report (Dec. 2010), available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Knutson_MN_2nd_InterimReport_AltApproaches_2010.pdf

Likewise, we propose to identify those groups of physicians that have cost composite scores that are statistically different from the mean cost composite score of all groups of physicians. We propose to classify these groups of physicians into high, average, and low cost categories based on whether they are significantly above, not different from, or below the mean cost composite score as described above with reference to quality composite. We propose to assess meaningful differences as those performance scores that are at least one standard deviation from the mean and we propose to assess precision at the 5.0 percent level of significance. We seek comment on these proposals and on whether we should only examine meaningful differences that are at least two or three standard deviations away from the mean. We also seek comment on whether to define the high and low categories of the cost composites as a fixed percentage (for example, 2.5 percent) of the number of groups of physicians or of the amount of payments under the PFS.

We propose to compare quality of care composite classification with the cost composite classification to determine the value-based payment modifier adjustment according to the amounts in Table 70.

**TABLE 70: Value-Based Payment 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 reporting measures and average beneficiary risk score in the top 25 percent of all risk scores.

We propose to establish the upward payment adjustment factor ("x") after the performance period has ended based on the aggregate amount of downward payment adjustments. We also propose to aggregate the downward payment adjustments in Table 70 with the downward adjustment for groups of physicians with 25 or more eligible professionals first

and then to solve for the upward payment adjustment factor ("x"). For example, after determining the aggregate projected amount of the downward payment adjustments, CMS could calculate that the payment adjustment factor ("x") would be 0.75 percent such that high quality/low cost groups of physicians would receive a 1.5 percent (2 x 0.75) upward payment adjustment during the payment adjustment period.

We also propose an additional incentive for groups of physicians to furnish care to high-risk Medicare beneficiaries. We seek to ensure that the value-based payment modifier does not cause unintended consequences in which groups of physicians decline to treat the most difficult cases. In particular, we propose that the scoring methodology provide a greater upward payment adjustment (+1.0x) for 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, claims, registries, or EHRs. We propose to increase the upward payment adjustment to +3x (rather than +2x) for groups of physicians classified as high quality/low cost and to +2x (rather than +1x) for groups of physicians that are either high quality/average cost or average quality/low cost if the group of physicians' attributed patient population has an average risk score that is in the top 25 percent of all beneficiary risk scores. In other words, we are not proposing this additional upward payment adjustment (+1.0x) for groups of physicians that select the PQRS administrative claims-based reporting option.

We propose this quality-tiering scoring methodology because it compares the quality of care furnished to cost as required by the statute. It also allows physicians to understand clearly how their payment is affected by their scores on the quality of care and cost composites. We also believe it is a reasonable way to start to modify physician payment because it clearly distinguishes the outliers (for example, high quality/low cost compared to low quality/high cost)

from mean performance. The framework also allows us to fine tune payment adjustments as we gain greater experience with the proposed methodologies.

We seek comment on this proposal and on the proposed scoring methodologies. We seek comment in particular on whether it is appropriate to apply the same upward payment adjustment in Table 70 to groups of physicians classified as high quality/medium cost and medium quality/low cost. In addition, we seek comment on whether we should not provide as great an upward payment adjustment for those groups of physicians that select to report under the PQRS via the administrative claims-based reporting option, so that we encourage greater PQRS participation.

(2) Total Performance Score

A second approach to scoring the value-based payment modifier is a total performance score approach. This approach allows us to develop a unique value-based payment modifier for each group of physicians. This approach results in a range of continuous payment adjustments rather than the thresholds proposed in the quality tier approach. Under this approach, we could calculate a total performance score (TPS) by equally weighting the quality of care and cost composites. A negative score for the quality composite (Physician Group 2 in Table 71) means the group of physicians performed below the national average on the relevant quality measures. Likewise, a negative score for the cost composite means the group of physicians had higher costs than the national average. A score of zero means that the group of physicians performed at the national average. The example in Table 71 illustrates how we could calculate the TPS for three groups of physicians. In this example, Physician Groups 1 and 3 are above average and Physician Group 2 is below average.

**TABLE 71: Example of Total Performance Score**

| | **Quality Composite (50%)** | **Cost Composite (50%)** | **TPS** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Physician Group 1 | .9 | .2 | **.55** |
| Physician Group 2 | -.9 | -1.2 | **-1.05** |
| Physician Group 3 | 2.2 | 1.2 | **1.70** |

We could develop an exchange function in which we translated the TPS into a unique value-based payment modifier for each group of physicians. This method would be similar to the approach we use in the Hospital Value-Based Purchasing program where we use a linear exchange function to develop a unique payment for each hospital. This approach results in a continuous array of unique value-based payment modifiers such that there are no longer cut-off points between high and low performing groups of physicians. Rather, each group of physicians' payment would be modified under this approach.

We believe the quality-tiering approach may better compare the quality of care furnished to costs. We also believe that the quality-tiering approach is more transparent because groups of physicians may be more aware of the level at which quality and cost performance is likely to result in payment adjustment. However, we seek comment on these observations and whether to use the total performance score methodology rather than the quality-tiering methodology for the value-based payment modifier. If we were to use a total performance score methodology, we also seek comment on the weights to be given to quality and cost composites.

i. Proposed Informal Review and Inquiry Process

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the value-based payment modifier;
- The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care;
- The evaluation of costs composite, including establishment of appropriate measures of

costs;

- The dates of implementation of the value-based payment modifier;
- The specification of the initial performance period and any other performance period;
- The application of the value-based payment modifier; and
- The determination of costs.

Despite the prohibition of administrative and judicial review, we believe it is useful for groups of physicians to understand how their payment under the PFS could be changed by the value-based payment modifier. We also believe that a mechanism is needed for groups of physicians to review and to identify any possible errors prior to application of the value-based payment modifier.

Therefore, we intend to disseminate Physician Feedback reports containing calendar year 2013 data in the fall of 2014 that encompass all physicians (individually or in groups of physicians, as applicable); these reports would be the basis of the value-based payment modifier in 2015. We propose that these reports would contain, among other things, the quality and cost measures and measure performance and benchmarks used to score the composites, and quality of care and cost composite scores, and the value-based payment modifier amount.

After the dissemination of the Physician Feedback reports in the fall of 2014, we propose that physicians would be able to e-mail or call a technical help desk to inquire about their report and the calculation of the value-based payment modifier. We envision this process to help educate and inform physicians about the value-based payment modifier, especially for those groups of physicians that have elected that their value-based payment modifier be calculated using a quality-tiering approach. We note that because we have proposed to align our proposals with the PQRS satisfactory reporting criteria, groups of physicians will be able to avail themselves of the informal review process regarding the PQRS payment adjustment as well. We

do not envision providing opportunities for review of a value-based payment modifier.

In anticipation of the reports that we would produce in 2014, in the fall of 2013 we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals based on 2012 data. These reports will include a "first look" at the methodologies we are proposing in this rule for the value-based payment modifier. We view these reports as a way to help educate groups of physicians about how the value-based payment modifier could affect their payment under the PFS.

j. Physician Scenario and the Value-Based Payment Modifier Proposals

The following example summarizes and pulls together our proposals for the payment modifier based on a group of physicians that satisfactorily reports quality measures through the PQRS GPRO web-interface and elects to have the value-based payment modifier calculated using the proposed quality-tiering methodology.

- Quality measures: A large medical practice group with more than 100 physicians each billing under the same TIN could choose to submit data on a common set of quality measures via the PQRS web-interface. This group of physicians would need to meet the applicable and proposed self-nomination requirements under the PQRS to report data under this option. After approval to participate, CMS would provide the group of physicians in early 2014 a list of patients pre-loaded into the GPRO web-interface on which they would be required to report the measures to CMS. They would complete the web-interface during the first calendar quarter of 2014.

- Composite quality score: To arrive at the quality composite score, we would create a standardized score for each quality measure included in the GPRO web-interface and then combine these scores into the quality composite. Specifically, for each measure we would divide the difference between the group's performance rate and the benchmark (the national mean

computed across all groups of physicians and individual physicians submitting data on the quality measure) by the measure's standard deviation to create a standardized unit. Standardized units representing each measure are then combined into quality domains with each measure weighted equally. We would then equally weight the domains to form the quality composite score.

- Composite cost score: CMS will calculate five cost measures for the attributed beneficiaries. The standardized cost score composite is comprised of two cost domains: total per capita cost and condition-specific per capita costs. Each domain is weighted equally. For each cost measure, the difference between the group's performance and the national mean is divided by the standard deviation computed across all groups of physicians.

- Payment modifier: Using the quality composite, we would identify groups of physicians that have quality composite scores that are significantly different from the mean quality composite score of all groups of physicians. We would classify the groups of physicians into high, average, and low quality based on whether they are statistically above, not different from, or below the mean.

We would also identify groups of physicians that have cost composite scores that are significantly different from the mean cost composite score and classify groups of physicians into high, average, and low cost. We would then compare the quality of care composite classification with the cost composite classification to determine the payment modifier according to the amounts in Table 70.

Assuming the group of physicians had high quality and average cost, it would be eligible for an upward payment adjustment of +1x on each of its claims submitted for payment under the PFS during 2015. If the beneficiaries attributed to the group of physicians had an average risk score that was in the top 25 percent of all beneficiary risk scores, the upward payment adjustment

would be increased to +2x. We would indicate the exact amount of the upward payment adjustment in the Physician Feedback report that we produced in the fall of 2014.

(4) 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 September 2011, we produced and disseminated confidential feedback reports to physician groups that participated in the PQRS Group Practice Reporting Option (GPRO) in 2010, and in March 2012 we produced and disseminated reports to physicians practicing in the following States: Iowa, Kansas, Missouri, and Nebraska.

(a.) CY 2010 Physician Group Feedback Reports based on 2010 data and disseminated in 2011

In September 2011, we produced and distributed confidential Physician Feedback reports to each of the 35 medical group practices that participated in the 2010 GPRO of the PQRS. Each report provided information on the quality of care and resource use for Medicare FFS beneficiaries treated by the medical groups in 2010. More information about the methodologies used in these reports and the aggregate findings from these reports is available at http://www.cms.gov/physicianfeedbackprogram.

To participate in the 2010 PQRS GPRO, a group practice had to be a single provider entity, identified by its TIN, with at least 200 eligible professionals. Thirty-five groups, encompassing 24,823 eligible professionals, participated in the 2010 PQRS GPRO reporting option. On average, each group practice contained the following type of medical professionals: primary care (27 percent), medical specialties (20 percent), surgeons (13 percent), other medical professionals (36 percent) and ER physicians represented less than 1 percent. Despite the average group practice profile, five group practices were composed of substantially more

medical specialists and surgeons than primary care professionals. A professional's medical specialty was determined based on the CMS medical specialty code listed most often on their 2010 Part B claims.

For each of the 35 participating group practices, we attributed Medicare FFS beneficiaries to the group practice if eligible professionals in the group practice billed for at least two office visits or other outpatient E&M services and the group practice had the plurality of E&M charges for that beneficiary. The average beneficiary population attributed to a group practice was 12,550 beneficiaries with the smallest group practice attributed 2,424 beneficiaries and the largest with 31,006 beneficiaries.

In 2010, each beneficiary that was attributed to a group practice had an average of 10 total E&M visits in 2010 (both to physicians in and outside the group practice), ranging from a low of nine visits per group practice to a high of 14 visits per group practice. Seven of these E&M visits, on average, were with physicians in the group practice, ranging from a low of five E&M visits to a high of nine E&M visits with physicians in the group practice. Thus, the GPRO groups provided not only the plurality, but the large majority, of E&M visits to the beneficiaries attributed to that group practice. On average, the group practices accounted for 78 percent of attributed beneficiaries' E&M visits.

Primary care physicians, on average among all 35 groups, furnished over half (53 percent) of the plurality of E&M visits within the group practice, followed by medical specialists at 27 percent. Surgeons provided 11 percent of the plurality of E&M visits and other physicians furnished 9 percent. We note that for five group practices medical specialists, rather than primary care providers, furnished the plurality of care for the attributed beneficiaries.

Table 72 shows the mean performance rate and the performance rates for the 10th, 50$^{th}$, and 90$^{th}$ percentiles for each of the 26 quality measures that were included in the PQRS GPRO

measure set for 2010. We calculated the performance rates based on the data submitted by each of the group practices. Table 72 also shows the mean performance rate for those 19 measures that were included in the PQRS GPRO that eligible professionals also reported at an individual level through the PQRS. The mean group practice performance rate was equal to or higher than the individual performance rate for 16 of the 19 measures.

**TABLE 72: Performance Rates on 26 Quality Measures for Individual Eligible Physicians and Groups**

| Measure Number | Measure Title | 2010 Average Individual Performance Rate/Eligible Professional | Performance Rate for All 2010 GPROs | | | |
|---|---|---|---|---|---|---|
| | | | Mean | Percentile | | |
| | | | | 10th | 50th | 90th |
| **DIABETES** | | | | | | |
| GPRO DM-1 | Diabetes Mellitus: Hemoglobin A1C Testing | NA | 93% | 88% | 94% | 98% |
| GPRO DM-2* | Diabetes Mellitus: Hemoglobin A1C Poor Control in Diabetes Mellitus | 22% | 22% | 11% | 21% | 39% |
| GPRO DM-3 | Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus | 59% | 58% | 49% | 57% | 67% |
| GPRO DM-5 | Diabetes Mellitus: Low Density Lipoprotein ( LDL-C) Control in Diabetes Mellitus | 57% | 54% | 41% | 55% | 66% |
| GPRO DM-6 | Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients | 74% | 89% | 82% | 89% | 96% |
| GPRO DM-8 | Diabetes Mellitus: Foot Exam | 72% | 61% | 16% | 69% | 86% |
| GPRO DM-9 | Diabetes Mellitus: Lipid Profile | NA | 84% | 75% | 84% | 93% |
| **HEART FAILURE** | | | | | | |
| GPRO HF-1 | Heart Failure: Left Ventricular ( LVF) Assessment | 46% | 86% | 68% | 93% | 97% |
| GPRO HF-2 | Heart Failure: Left Ventricular ( LVF) Testing | NA | 86% | 68% | 90% | 98% |
| GPRO HF-3 | Heart Failure: Weight Measurement | NA | 86% | 79% | 88% | 96% |
| GPRO HF-5 | Heart Failure: Patient Education | 43% | 77% | 54% | 83% | 97% |
| GPRO HF-6 | Heart Failure: Beta Blocker Therapy for Left Ventricular Systolic Dysfunction ( LVSD) | 83% | 92% | 86% | 95% | 99% |
| GPRO HF-7 | Heart Failure: Angiotenson-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker ( ARB) Therapy for Left Ventricular Systolic Dysfunction ( LVSD) | 86% | 90% | 82% | 91% | 97% |
| GPRO HF-8 | Heart Failure: Warfarin Therapy For Patients With Atrial Fibrillation | 72% | 79% | 62% | 82% | 94% |
| **CORONARY ARTERY DISEASE** | | | | | | |

| Measure Number | Measure Title | 2010 Average Individual Performance Rate/Eligible Professional | Performance Rate for All 2010 GPROs | | | |
|---|---|---|---|---|---|---|
| | | | Mean | Percentile | | |
| | | | | 10th | 50th | 90th |
| GPRO CAD-1 | Coronary Artery Disease ( CAD): Oral Antiplatelet Therapy Prescribed for patients with CAD | 85% | 85% | 50% | 93% | 97% |
| GPRO CAD-2 | Coronary Artery Disease ( CAD): Drug Therapy for Lowering LDL- Cholesterol | 75% | 90% | 85% | 92% | 97% |
| GPRO CAD-3 | Coronary Artery Disease ( CAD): Beta Blocker Therapy for CAD Patients with Prior Myocardial Infarction | 71% | 87% | 76% | 88% | 95% |
| GPRO CAD-7 | Coronary Artery Disease ( CAD): Angiotensin-Converting Enzyme ( ACE) Inhibitor or Angiotensin Receptor Blocker ( ARB) Therapy for Patients with CAD and Diabetes and /or Left Ventricular Systolic Dysfunction ( LVSD) | 67% | 83% | 75% | 84% | 91% |
| | **HYPERTENSION** | | | | | |
| GPRO HTN-1 | Hypertension ( HTN): Blood Pressure Measurement | NA | 92% | 72% | 98% | 100% |
| GPRO HTN-2 | Hypertension ( HTN): Blood Pressure Control | NA | 68% | 58% | 68% | 76% |
| GPRO HTN-3 | Hypertension ( HTN): Plan of Care | NA | 56% | 21% | 61% | 79% |
| | **PREVENTIVE CARE AND SCREENING** | | | | | |
| GPRO PREV-5 | Preventive Care and Screening: Screening Mammography | 54% | 74% | 63% | 76% | 85% |
| GPRO PREV-6 | Preventive Care and Screening: Colorectal Cancer Screening | 52% | 60% | 37% | 64% | 76% |
| GPRO PREV-7 | Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old | 51% | 67% | 50% | 67% | 79% |
| GPRO PREV-8 | Preventive Care and Screening: Pneumonia Vaccination for Patients | 55% | 62% | 40% | 62% | 86% |

- DM-2 is a measure of poorly controlled blood sugar: Higher scores (and percentile rankings) on this measure reflect worse performance.

The group practice performance rates were statistically reliable at a high level across the vast majority of the measures. We examine reliability because the clinical measures are derived from samples of the group practice's attributed beneficiaries. In this context, reliability means the group practices' performance rates would be similar or the same if a different sample population of the group practice were used for quality measurement. The average reliability score for the group practices' quality measures related to coronary artery disease ranged from 0.86 to 0.99, for diabetes from 0.87 to 0.99, for heart failure from 0.79 to 0.99, for hypertension from 0.89 to 1.00, and for the preventive measures from 0.94 to 0.98. All groups' quality measures achieved at least a 0.50 score with most group practices well above that level.

The percentage of primary care physicians in a group practice did not correlate with higher performance on the clinical care measures, even though the 26 quality measures focused on effective primary care. As noted above, in five group practices, medical specialists rather than primary care providers furnished care to the majority of attributed beneficiaries. Two of these five group practices were among the top five group practices overall across all quality measures.

In addition to the 26 quality measures included in the GPRO, the reports also contained each group practice's performance on measures of avoidable hospitalizations for six ambulatory care sensitive conditions (ACSCs). These are conditions for which outpatient care can potentially prevent a hospital admission. The measures were based on measures developed by the Agency for Healthcare Research and Quality (AHRQ) and more information can be found at http://www.qualityindicators.ahrq.gov/modules/pqi_overview.aspx.

The six ambulatory care sensitive conditions include: (1) bacterial pneumonia; (2) urinary tract infection (UTI); (3) dehydration; (4) heart failure (HF); (5) chronic obstructive pulmonary disease (COPD); and (6) diabetes – a composite measure based on short-term diabetes complications, uncontrolled diabetes, long-term diabetes complications, and lower extremity amputation for diabetes. Table 73 shows the mean, as well as minimum, and maximum performance rate (as expressed in events per 1,000 beneficiaries) for each of the six ACSC measures of potentially preventable hospitalizations.

**TABLE 73: Performance Rates for the ACSCs**

| (ACSC) | Mean | Minimum | Maximum |
|---|---|---|---|
| Diabetes | 25 | 7 | 39 |
| COPD | 95 | 53 | 142 |
| CHF | 122 | 66 | 200 |
| Bacterial Pneumonia | 12 | 7 | 20 |
| UTI | 8 | 4 | 13 |
| Dehydration | 3 | 0 | 11 |

We also examined five measures of cost: total per capita costs for beneficiaries attributed to the group practice and total per capita for beneficiaries that had the following four chronic conditions: diabetes, heart failure, chronic obstructive pulmonary disease, and coronary artery disease.

In calculating these measures, we first standardized the Medicare payments to ensure fair comparisons. Geographic variations in Medicare payments to providers can reflect factors unrelated to the care provided to beneficiaries. All Medicare payments have been standardized such that a given service is priced at the same level across all providers within the same facility type or setting, regardless of geographic location or differences in Medicare payment rates among facilities. More information about how CMS standardized payments can be found in the September 2011 document describing the methodologies used in the 2010 QRURs, which can be accessed at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_GPRO_QRUR_Detailed_Methodology.pdf.

The standardized total per capita costs for the 35 group practices for attributed beneficiaries was on average, $13,135. Thus on average, Medicare paid providers $13,135 per beneficiary attributed to each group practice. The range of total per capita costs was $9,124 to $24,480 and an absolute difference of $15,536 per beneficiary.

We applied a risk adjustment methodology to adjust these total per capita costs for patient demographics, socioeconomic factors, and prior health conditions, recognizing that physiologic differences among beneficiaries can affect their medical costs, regardless of the care provided. This risk adjustment methodology is based on the CMS' Hierarchical Condition Categories (HCC) model that assigns ICD-9 diagnosis codes (each with similar disease characteristics and costs) to 70 clinical conditions to capture medical condition risk. The HCC

risk scores also incorporate patient age, general reason for Medicare eligibility (aged or disabled), and Medicaid eligibility. The risk adjustment model also included the beneficiary's end stage renal disease (ESRD) status. More information about how CMS risk adjusted per capita costs can be found in the September 2011 document describing the methodologies used in the 2010 QRURs, which can be accessed at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_GPRO_QRUR_Detailed_Methodology.pdf

After risk adjustment, the adjusted average total per capita costs was $12,652 with a range of $9,932 to $16,736 and an absolute difference of $6,804. Thus the risk adjustment methodology had the effect of reducing the absolute difference between the groups with the lowest and highest total per capita range 55.7 percent. In particular, the lowest third of the groups were adjusted upward by an average of 6.2 percent and the most expensive third were lowered by 10.4 percent. The middle third, on average, were adjusted downward by 0.1 percent, but the range of adjustments was -10.3 to +8.2 percent.

Moreover, three of the five group practices for which medical specialists provided the plurality of care to attributed beneficiaries had their costs risk adjusted downward. Two of these five groups had their unadjusted per capita costs adjusted upward.

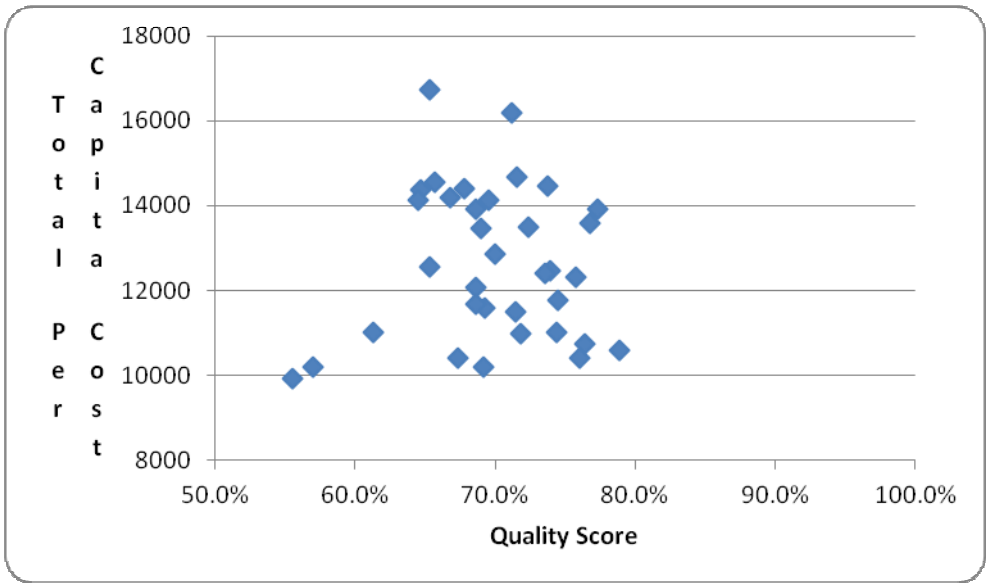
The physician feedback reports also showed the percentage of professionals who did not bill under the group practice's TIN who treated the beneficiaries attributed to the group practice. On average, 42 percent of the professionals that cared for attributed patients were outside the group practice. The range was from 18 to 84 percent. We also found a weak association between the percent of professionals who did not bill under the group practice's TIN and total per capita costs for the attributed beneficiaries. The correlation was 0.12.

All 35 group practices achieved statistical reliability scores greater than 0.70 for the

overall per capita cost measures and the four subgroup-specific cost measures. In particular, the group practices achieved an average reliability score of 0.99 for the overall per capita cost measure. In addition, all 35 group practices achieved a reliability of greater than 0.70 across all sub cost categories. The average reliabilities were 0.93 for heart failure, 0.91 for COPD, 0.95 for diabetes, and 0.96 for CAD.

Although the sample of group practices was small (35), we found almost no association between quality of care furnished and the total risk-adjusted per capita cost for each group practice. We constructed a simple quality score by taking the average of the 32 performance rates (26 clinical quality measures and six ACSC rates). We translated the ACSC rates into percentages with the lowest ACSC rate equal to 100.0 percent (because lower rates are better) and the highest ACSC rate equal to 0.0 percent. Table 74 shows a scatter diagram of the relationship between the quality of care furnished by each group practice and the total risk-adjusted per capita cost. The correlation between the two variables is 2.0 percent.

**TABLE 74: Quality of Care Compared To Cost**




(b.) Individual Physician Feedback reports based on 2010 data and disseminated in 2012.

In March 2012, we produced and made available for download confidential individual Physician Feedback reports for 23,730 physicians enrolled in Medicare and practicing in Iowa, Kansas, Missouri, and Nebraska. Each report provided information on the quality of care and resource use for Medicare FFS beneficiaries treated by the physician in 2010. Each report contained two sets of quality measures for Medicare beneficiaries: measures physicians reported in the PQRS via the claims-based reporting methodology, and quality measures calculated by CMS that relied solely on Medicare administrative claims data.

Approximately 25 percent (5,891) of the 23,730 physicians reported on one or more PQRS measure in 2010. The five specialties with the highest participation rates, as a percentage of the total number of physicians in that specialty, were Ophthalmology, Anesthesiology, Gynecology/Oncology, Pathology, and Geriatric Medicine. Physicians reported 3.7 PQRS measures on average. The maximum number of measures reported was 30, by a family practitioner.

The PQRS performance rates were strongly skewed upward and compressed for the physicians in the four states. For approximately three quarters of the measures, the 50$^{th}$ percentile was 100 percent. For approximately one-third of the measures, the 25$^{th}$ percentile was 100 percent. The most frequently reported PQRS measure was "Health Information Technology: Adoption/Use of Electronic Health Records", reported by 1,494 physicians (6.3 percent). The 2010 Reporting Experience report has more information on PQRS performance rates nationwide and it is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRI.

The reports also contained information on up to 28 administrative claims-based quality measures (and 13 sub-measures for a total of 41 measures) depending upon whether the physician treated at least one beneficiary that was eligible for the measure, that assessed

whether Medicare FFS beneficiaries received recommended primary care and preventive care services. We calculated these measure performance rates solely from Medicare FFS claims data. The measurement year used for calculating performance was January 1 - December 31, 2010; claims were available for a one-year look-back period to January 1, 2009, for measures requiring a look-back period. Specifications for these measures are available at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf.

On average, a physician's report contained information on 30 of 41 measures. The reports provided this information for any beneficiary to whom the physician furnished at least one service, even if the physician did not provide the treatment indicated by the quality measure. We provided this information because we believe it is critical to inform physicians about the quality of care that their beneficiaries received for primary care and preventive services from any Medicare FFS physician. Moreover, physicians may be unaware of the care that that their beneficiaries receive. Table 75 shows the percentage of Medicare FFS patients who received the treatment indicated by the quality measure. There is room for improvement for physicians to provide basic recommended services in many clinical areas, especially those where the percentage of beneficiaries receiving the indicated treatment is less than 50 percent.

**TABLE 75: Physician Performance on Medicare Claims–Based Quality Measures for 2010 QRUR Physicians (Iowa, Kansas, Missouri, Nebraska)**

| Clinical Condition and Measure<br>Specifications for these clinical measures are posted at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf. | Mean Performance Rate<br>Physicians in Iowa, Kansas, Missouri, and Nebraska | |
|---|---|---|
| | Number of Physicians Included | Percentage of Medicare Patients Who Received the Service |
| **Chronic Obstructive Pulmonary Disease (COPD)** | | |
| **Pharmacotherapy Management of COPD Exacerbation** | | |
| 1. Dispensed Systemic Corticosteroid Within 14 Days of Event | 18,472 | 66% |
| 2. Dispensed Bronchodilator Within 30 Days of Event | 18,472 | 66% |

| Clinical Condition and Measure<br>Specifications for these clinical measures are posted at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf. | Mean Performance Rate Physicians in Iowa, Kansas, Missouri, and Nebraska | |
|---|---|---|
| | Number of Physicians Included | Percentage of Medicare Patients Who Received the Service |
| **Use of Spirometry Testing to Diagnose COPD** | 22,290 | 33% |
| **Bone, Joint, and Muscle Disorders** | | |
| **Osteoporosis Screening for Chronic Steroid Use** | 17,046 | 58% |
| **Osteoporosis Management in Women ≥ 67 Who Had a Fracture** | 19,678 | 14% |
| **Disease-Modifying Antirheumatic Drug Therapy for Rheumatoid Arthritis** | 18,094 | 77% |
| **Cancer** | | |
| **Breast Cancer Surveillance for Women with a History of Breast Cancer** | 15,550 | 78% |
| **PSA Monitoring for Men with Prostate Cancer** | 17,598 | 89% |
| **Diabetes** | | |
| **Dilated Eye Exam for Beneficiaries ≤ 75 with Diabetes** | 23,012 | 71% |
| **HbA1c Testing for Beneficiaries ≤ 75 with Diabetes** | 23,012 | 87% |
| **Urine Protein Screening for Beneficiaries ≤ 75 with Diabetes** | 23,012 | 74% |
| **Lipid Profile for Beneficiaries ≤ 75 with Diabetes** | 23,012 | 77% |
| **Gynecology** | | |
| **Endometrial Sampling or Hysteroscopy with Biopsy Before Endometrial Ablation Procedure** | 3,704 | 53% |
| **Heart Conditions** | | |
| **Statin Therapy for Beneficiaries with Coronary Artery Disease** | | |
| 1. Percentage Prescribed Statin Therapy | 20,909 | 71% |
| 2. Average Medication Possession Ratio* | 20,172 | 80% |
| 3. Percentage with Medication Possession Ratio ≥ 0.80* | 20,172 | 64% |
| **Persistence of Beta Blocker Treatment After Heart Attack** | 10,381 | 57% |
| **Lipid Profile for Beneficiaries with Ischemic Vascular Disease** | 22,130 | 44% |
| **Human Immunodeficiency Virus (HIV)** | | |
| **Monitoring for Disease Activity for Beneficiaries with HIV** | 13,345 | 39% |
| **Mental Health** | | |
| **Antidepressant Treatment for Depression** | | |
| 1. Acute Phase Treatment (at least 12 weeks) | 16,224 | 54% |
| 2. Continuation Phase Treatment (at least 6 months) | 16,224 | 39% |
| **Follow-Up After Hospitalization for Mental Illness** | | |
| 1. Percentage of Patients Receiving Follow-Up Within 30 Days | 18,562 | 63% |
| 2. Percentage of Patients Receiving Follow-Up Within 7 Days | 18,562 | 33% |
| **Prevention** | | |
| **Breast Cancer Screening for Women ≤ 69** | 23,021 | 64% |
| **Medication Management** | | |
| **Viral Load Testing for Beneficiaries with Antiviral Therapy for Hepatitis C** | 1,212 | 93% |
| **Lipid Profile for Beneficiaries Who Started Lipid-Lowering Medications** | 22,632 | 41% |
| **Annual Monitoring for Beneficiaries on Persistent Medications** | | |
| 1. Angiotensin Converting Enzyme (ACE) Inhibitors or Angiotensin Receptor Blockers (ARB) | 22,010 | 93% |
| 2. Digoxin | 15,167 | 93% |

| Clinical Condition and Measure<br>Specifications for these clinical measures are posted at http://www.cms.gov/PhysicianFeedbackProgram/Downloads/claims_based_measures_with_descriptions_num_denom_excl.pdf. | Mean Performance Rate Physicians in Iowa, Kansas, Missouri, and Nebraska | |
|---|---|---|
| | Number of Physicians Included | Percentage of Medicare Patients Who Received the Service |
| 3. Diuretics | 21,905 | 93% |
| 4. Anticonvulsants | 1,712 | 39% |
| 5. Total Rate (sum of 4 previous numerators divided by sum of 4 previous denominators) | 22,385 | 92% |
| **Anticoagulation Treatment ≥ 3 Months After Deep Vein Thrombosis** | 14,787 | 43% |
| **Anticoagulation Treatment ≥ 3 Months After Pulmonary Embolism** | 10,298 | 44% |
| **International Normalized Ratio (INR) Testing for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications** | 14,006 | 14% |
| *NOTE: For the measures shown below, **lower percentages reflect better performance*** | | |
| **Drugs to Be Avoided for Beneficiaries ≥ 65** | | |
| 1. Patients Who Receive at Least One Drug to Be Avoided | 23,085 | 27% |
| 2. Patients Who Receive at Least Two Different Drugs to Be Avoided | 23,085 | 16% |
| **Potentially Harmful Drug-Disease Interactions for Beneficiaries ≥ 65** | | |
| 1. Prescription for Tricyclic Antidepressants, Antipsychotics, or Sleep Agents for Patients with a History of Falls | 21,132 | 18% |
| 2. Prescription for Tricyclic Antidepressants or Anticholinergic Agents for Patients with Dementia | 21,443 | 29% |
| 3. Prescription for Nonaspirin NSAIDs or Cox-2 Selective NSAIDs for Patients with Chronic Renal Failure | 16,902 | 8% |
| 4. Total Rate (sum of 3 previous numerators divided by sum of 3 previous denominators) | 22,232 | 22% |
| **Lack of Monthly INR Monitoring for Beneficiaries on Warfarin** | 21,967 | 48% |

*Unlike the other measures in this table, these values represent a ratio, not a percentage of patients receiving the service.

The reports also provided information on five measures of per capita cost. Total per capita costs for beneficiaries attributed to the physician and total per capita costs for beneficiaries that had the following four chronic conditions: diabetes; heart failure; chronic obstructive pulmonary disease (COPD); and coronary artery disease (CAD). As discussed earlier, we standardized and risk adjusted the total per capita cost measures.

To assess per capita cost measures, we attributed beneficiaries to physicians. To attribute beneficiaries, the reports classified each physician's Medicare FFS beneficiaries into three groups based upon the degree of the physician's involvement with the patient:

- Directed: The physician billed for 35 percent or more of the patient's office or other outpatient Evaluation and Management (E&M) visits.

- Influenced: The physician billed for fewer than 35 percent of the patient's outpatient E&M visits, but for 20 percent or more of the patient's total professional costs.
- Contributed: The physician billed for fewer than 35 percent of the patient's outpatient E&M visits, and for less than 20 percent of the patient's total professional costs.

As discussed with reference to the value-based payment modifier, this attribution methodology assigns the same patient to all physicians who treated the patient, but classifies the patient based on how involved the physician was with the care provided to the patient.

Table 76 shows the number of beneficiaries attributed, on average, to physicians under each of these rules. We wish to highlight two observations. First, that primary care physicians generally furnished services to fewer patients than surgeons/specialists and other types of physicians (which included radiologists, anesthesiologists, and pathologists) and that primary care physicians directed care more often than other types of physicians. Second, there were several physicians in all categories who only contributed to care, meaning that care can frequently be fragmented. This finding highlights the importance of coordinating care among physicians.

**TABLE 76: Beneficiaries in Iowa, Kansas, Missouri, and Nebraska Attributed by Physician Type: Average Number of Beneficiaries**

| Type of Physician | Average Number of Attributed Beneficiaries | Average Number of Directed Beneficiaries | Average Number of Influenced Beneficiaries | Average Number of Contributed Beneficiaries |
|---|---|---|---|---|
| Primary care | 279 | 105 | 13 | 181 |
| Medical specialist | 471 | 59 | 51 | 381 |
| Surgeons | 309 | 36 | 64 | 217 |
| Emergency medicine | 367 | 35 | 14 | 350 |
| Other | 860 | 18 | 34 | 840 |

We calculated total per capita costs for each type of attribution of patients. As discussed

above and shown in Table 77, the beneficiaries who receive care under the "contributed only" attribution have substantially higher per capita costs and accounted for 20 percent of those beneficiaries covered by the 2010 individual reports.

**TABLE 77: Mean Total Per Capita Costs in the QRURs**

| Type of Physician | Overall | Directed | Influenced | Contributed |
|---|---|---|---|---|
| Primary care | $16,580 | $9,733 | $6,780 | $19,019 |
| Medical specialist | 19,765 | 11,256 | 9,219 | 21,276 |
| Surgeons | 17,535 | 11,482 | 15,182 | 18,313 |
| Emergency medicine | 20,729 | 10,389 | 3,675 | 21,217 |
| Other | 23,704 | 11,442 | 8,987 | 23,980 |

(c.) Physician Feedback Program Dissemination Strategy

Based on our previous dissemination of individual Physician Feedback reports, we have learned that the overwhelming factor that prevents physicians from accessing their reports is lack of knowledge of their availability. We undertook several steps this year to increase awareness of the Physician Feedback reports. First, we increased the information we provided to physicians about the feedback reports, performance reporting, the value-based payment modifier, and our methodology via www.cms.gov/physicianfeedbackprogram, fact sheets, FAQs, video, slides, national provider calls, targeted conference calls with report recipients, meetings with national and local medical associations and specialties, and multiple physician fee for service list serve announcements. We also partnered with the J5 Medicare Administrative Contractor (MAC), WPS, for Iowa, Kansas, Nebraska, and Missouri, to develop a secure internet portal where physician could easily obtain their reports. As of June 10, 2012, 7,484 of approximately 24,000 (31 percent) individual Physician Feedback reports have been accessed electronically. This is a substantial increase from earlier phases of the Physician Feedback program in which only 1 percent of physicians obtained their reports.

We also have aggressively solicited feedback from physicians and physician groups, including the American Medical Association, on how to increase the usefulness of the reports so that physicians and groups of physicians would actively seek this type of information from CMS. We invited report recipients (via several conference calls directed first to medical practice groups and then individual physicians) to provide us input on the usefulness and credibility of the performance measures, and other information contained in the reports so that we can improve the reports for future years.

Following the September 26, 2011 distribution of reports to physician groups, we hosted two conference calls for the 35 large medical practice groups. In addition to "walking through" a sample template of the group performance report, we responded to questions and followed up with an aggregation of questions/issues raised by groups and corresponding answers and explanations from CMS. These reports represent the first time performance on a wide-range of quality and cost measures can be viewed in the same report for Medicare beneficiaries in large group practices across the country.

After the March 2012 dissemination of individual reports, we conducted National Provider Calls on April 3, 2012 and April 5, 2012 at which time we reported some initial observations, reviewed a report template page by page, and answered questions from the call participants. On May 8, 2012 and June 4, 2012, we held another call in conjunction with the MAC, WPS, to obtain targeted feedback on the feedback reports and how they could be improved and made more useful. We view the physician feedback reports as a way to test various methods of analyzing and displaying comparative performance information and previewing methods that will be further developed for use in the value-based payment modifier. In addition, we have responded to over 50 requests for more information from the Help Desk we established for the program.

(d.) Future Plans for the Physician Feedback Reports

In the fall of 2012, we plan to disseminate Physician Feedback reports to all physicians in nine states (California, Iowa, Illinois, Kansas, Michigan, Minnesota, Missouri, Nebraska, and Wisconsin) based on 2011 data. These reports will contain the PQRS measures that physicians in these states submitted via enhanced claims, as well as information on 28 administrative claims measures included in the 2010 reports. We also will produce and disseminate Physician Feedback reports to the groups of physicians that reported measures through the PQRS GPRO web interface in 2011. We have adjusted and improved the content and organization of the Physician Feedback reports that we plan to produce later this year based on the comments we received from the Program Year 2010 report recipients. We plan to increase our outreach efforts to encourage physicians to view their reports, to begin to understand the methodologies we have proposed for the value-based payment modifier and that are included in the 2011 reports, and to provide suggestions on how we can make these reports more meaningful and actionable in the future.

In the fall of 2013, we plan to produce and disseminate Physician Feedback reports at the TIN level to all groups of physicians with 25 or more eligible professionals and to individual physicians that satisfactorily reported measures through PQRS in 2012 using any of the PQRS reporting mechanisms. These reports will include a “first look” at the methodologies that we are proposing in this rule for the value-based payment modifier.

In addition, section 1848(n) of the Act requires that we use the episode-based costs in the Physician Feedback reports beginning in 2013 for the reports based on 2012 data. As discussed above in relation to the value-based payment modifier, we plan to include episode-based cost measures for several episode types in these Physician Feedback reports. In addition, we plan to consider adjusting the format and organization of the reports, to the extent

practicable, to address the best practices outlined in the AMA's Guidelines for Reporting Physician Data. We believe that this dissemination plan satisfies our obligations under the section 1848(p)(4)(B)(ii)(II) of the Act to provide information to physicians and groups of physicians about the quality of care furnished to Medicare FFS beneficiaries.

In the fall of 2014, we plan to disseminate Physician Feedback reports based on 2013 data that show the amount of the value-based payment modifier and the basis for its determination. We plan to provide these reports to all groups of physicians (at the TIN level) with 25 or more eligible professionals. We are examining whether we can provide reports to groups of physicians with fewer than 25 eligible professionals and to individual level reports as well. These reports will contain, among other things, performance on the quality and cost measures used to score the composites and the value-based payment modifier amount. As discussed above, we anticipate providing an opportunity for review and correction as outlined in our value-based payment modifier proposals above.

L. Medicare Coverage of Hepatitis B Vaccine

1. Modification of high risk groups eligible for Medicare Part B coverage of Hepatitis B vaccine.

a. Background and Statutory Authority – Medicare Part B Coverage of Hepatitis B Vaccine

Section 1861(s)(10)(B) of the Act authorizes Medicare Part B coverage of hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. High and intermediate risk groups are defined in regulations at §410.63.

On December 23, 2011, the United States Centers for Disease Control and Prevention (CDC) published a Morbidity and Mortality Weekly Report, which included an article entitled "Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." The article stated that "In the United

States, since 1996, a total of 29 outbreaks of HBV [Hepatitis B virus] infection in one or multiple long-term care (LTC) facilities, including nursing homes and assisted-living facilities, were reported to CDC; of these, 25 involved adults with diabetes receiving assisted blood glucose monitoring. These outbreaks prompted the Hepatitis Vaccines Work Group of the Advisory Committee on Immunization Practices (ACIP) to evaluate the risk for HBV infection among all adults with diagnosed diabetes."

"HBV is highly infectious and environmentally stable; HBV can be transmitted by medical equipment that is contaminated with blood that is not visible to the unaided eye. Percutaneous exposures to HBV occur as a result of assisted monitoring of blood glucose and other procedures involving instruments or parenteral treatments shared between persons. Lapses in infection control during assisted blood glucose monitoring that have led to HBV transmission include multipatient use of finger stick devices designed for single-patient use and inadequate disinfection and cleaning of blood glucose monitors between patients. Breaches have been documented in various settings, including LTC facilities, hospitals, community health centers, ambulatory surgical centers, private offices, homes, and health fairs." Additionally, in analyses of persons without hepatitis B-related risk behaviors (that is, injection-drug use, male sex with a male, and sex with multiple partners), persons aged 23 through 59 years with diabetes had 2.1 times the odds of developing acute hepatitis B as those without diabetes; and the odds for hepatitis B infection were 1.5 times as likely for persons aged 60 and older. (MMWR, December 23, 2011).

Based on the Hepatitis Vaccines Work Group findings, ACIP recommended that:

- Hepatitis B vaccination should be administered to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years.
- Hepatitis B vaccination may be administered at the discretion of the treating clinician

to unvaccinated adults with diabetes mellitus who are aged 60 years and older.

b. Implementation

Based on the ACIP recommendations, we propose to modify §410.63(a)(1), High Risk Groups, by adding new paragraph "(viii) persons diagnosed with diabetes mellitus." Since HBV can be transmitted by medical equipment (that is, finger stick devices and blood glucose monitors) that is contaminated with blood that is not visible to the unaided eye, we believe that persons diagnosed with diabetes mellitus should be added the high risk group. Since lapses in infection control have been reported in both community and facility settings, the increased risk of contracting HBV is not limited to the facility setting. We believe that expanding coverage of Hepatitis B vaccinations and administration to those diagnosed with diabetes mellitus is supported by the findings and evidence reviewed by the Hepatitis Vaccines Work Group and the ACIP recommendations. Hepatitis B vaccination is a preventive measure that needs to occur before exposure. It is difficult to predict which diabetics will eventually be exposed in the circumstances that we discussed above. Therefore, we are proposing to expand coverage for hepatitis B vaccine and its administration to all individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities, for example, in nursing homes.

M. Updating Existing Standards for E-prescribing under Medicare Part D and Lifting the LTC exemption.

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 Social Security Act (the Act) to establish a voluntary prescription drug benefit program at section 1860D-4(e) of the Social

Security Act. Among other things, 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

(a) Adopting and updating:

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. One of these standards, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004 (excluding the Prescription Fill Status Notification Transaction and its three business cases; Prescription Fill Status Notification Transaction--Filled, Prescription Fill Status Notification Transaction--Not Filled, and Prescription Fill Status Notification Transaction--Partial Fill), hereafter referred to as

the NCPDP SCRIPT 5.0, is the subject of several of the proposals in this rule. CMS 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, version 1.0 of the NCPDP Formulary and Benefit standard, Implementation Guide, Version 1, Release 0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) is also one of the subjects 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.

(b) Exemption from the NCPDP SCRIPT standard in long term care settings (LTC)

While 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 generally required to comply with any applicable standards that are in effect at the time of their transmission, the early versions of the NCPDP SCRIPT standard did not support the complexities of the prescribing process for patients in long term care facilities where the prescribing process involves not only a prescriber and a pharmacy, but also a facility and its staff. As such, we exempted such entities from use of the NCPDP SCRIPT standard. That exemption, currently found at §423.160(a)(3)(iv), provides an exemption for entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser.

For a more detailed discussion, see the November 7, 2005 final rule (70 FR 67583).

(2) Updating e-Prescribing Standards

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, however, 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. CMS utilized this streamlined process when it published an interim final rule with comment on June 23, 2006 (71 FR 36020). That rule recognized NCPDP SCRIPT 8.1 as a backward compatible update to the NCPDP SCRIPT 5.0, thereby allowing for use of either of the two versions in the Part D program. Then, on April 7, 2008, CMS used notice and comment rulemaking (73 FR 18918) to finalize the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard. Finally, on July 1, 2010, CMS utilized the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible update of NCPDP SCRIPT 8.1 in an interim final rule (75 FR 38026).

In contrast to the extensive updating that was done to the NCPDP SCRIPT standard in the Part D e-prescribing program, the original NCPDP Formulary and Benefit 1.0 is still in place as the official Part D e-prescribing standard.

2. Proposals for Calendar Year 2013

a. Proposed Finalization of NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1, Retirement of NCPDP SCRIPT 8.1 and Adoption of NCPDP SCRIPT 10.6 as the official Part D E-Prescribing Standard

As described in greater detail below, we propose to finalize our recognition of NCPDP SCRIPT 10.6 as a backward compatible version of the official Part D e-prescribing standard NCPDP SCRIPT 8.1, effective from the effective date of the final rule through October 31, 2013, but, in response to the comments that were received to the interim final rule with comment, we also propose to retire NCPDP SCRIPT 8.1 effective October 31, 2013, and we propose to adopt NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard effective November 1, 2013.

On July 1, 2010, we published an interim final rule with comment (75 FR 38026) which named NCPDP SCRIPT 10.6 as a backward compatible update to NCPDP SCRIPT 8.1. We received 7 timely public comments on this interim final rule with comment. The comments came from a standards setting organization, two national industry associations, two healthcare organizations and, two health information intermediaries. All commenters supported the voluntary use of NCPDP SCRIPT version 10.6 as a backward compatible version of the adopted NCPDP SCRIPT 8.1 standard. Five of the commenters recommended that Version 10.6 be adopted as the official standard for the Medicare Part D E-Prescribing Program with a time frame of full implementation of January 1, 2013. One commenter recommended that CMS adopt version 10.6 as the official Part D e-prescribing standard, and retire version 8.1, but did not suggest a date by which that should happen. Another commenter recommended that CMS adopt version 10.6 as early as January 1, 2012. All commenters agreed that version 8.1 should be retired when version 10.6 was adopted.

As we discussed in the July 1, 2010 interim final rule with comment (75 FR 38026) NCPDP SCRIPT 10.6 has a number of new functionalities that, if users elect to use them will

mesh with their use of the adopted NCPDP SCRIPT 8.1, which was adopted in the April 7, 2008 e-prescribing final rule (73 FR 18918). These new functions would allow users drug NDC source information, pharmacy prescription fill numbers and date of sale information that could then be used in a medication history response. These added functionalities would therefore be expected to facilitate better record matching, the identification and elimination of duplicate records, and the provision of richer information to the prescriber between willing trading partners. We therefore agree with commenters that NCPDP SCRIPT 10.6 would be appropriate as an official standard for the Medicare Part D e-Prescribing Program. At the time of this rule's drafting, however, the suggested dates for the adoption of SCRIPT Version 10.6 as the official Part D e-prescribing standard and the retirement of NCPDP SCRIPT 8.1 have either passed or are too near in the future to be a reasonable implementation date. Furthermore, since the time of these comments, industry stakeholders have worked with NCPDP, a standards development organization, and reached out to CMS with additional suggestions for appropriate implementation dates in light of the current state of the standards development process. Stakeholders working though NCPDP currently recommend retiring NCPDP SCRIPT 8.1 on October 31, 2013 and adoption of NCPDP Script 10.6 as the official Part D e-prescribing standard on November 1, 2013. We believe that this is a realistic timetable to retire NCPDP SCRIPT 8.1 and the adopt NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard on the dates described.

As such, we propose to revise §423.160(b)(2)(ii) so as to limit its application to transactions on or before October 31, 2013 and add a new §423.160(b)(2)(iii) to require that, as of November 1, 2013, providers and dispensers use NCPDP SCRIPT 10.6 for the following electronic transactions that convey prescription or prescription related information:

- Get message transaction.

- Status response transaction.
- Error response transaction.
- New prescription transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill prescription request transaction.
- Refill prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction
- Fill status notification.

Furthermore, we propose to amend §423.160(b)(1) by adding a new 423.160(b)(1)(iii) to amend the information about which subsequent requirements in the section are applicable to which timeframes and amend §423.160(b)(1)(ii) to limit its application to transactions on or before October 31, 2013.

As considerable time has passed since we solicited comments on the retirement of NCPDP SCRIPT 8.1, we are soliciting additional comments regarding the retirement of version 8.1 on October 31, 2013. We also are soliciting comments on the adoption of Version 10.6 as the official Part D e-prescribing standard for the e-prescribing functions that will be outlined in §423.160(b)(1)(iii) and (b)(2)(iii), effective November 1, 2013.

b. Proposed Recognition of NCPDP Formulary and Benefit Standard 3.0 as a Backward Compatible Version of the NCPDP Formulary and Benefit Standard 1.0, Proposed Retirement of

NCPDP Formulary and Benefit Standard 1.0 and Proposed Adoption of NCPDP Formulary and Benefit Standard 3.0

Formulary and Benefits standards provide 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).

The NCPDP Formulary and Benefits Standard 1.0 enables the prescriber to consider this information during the prescribing process, and make the most appropriate drug choice without extensive back-and-forth administrative activities with the pharmacy or the health plan.

As discussed above, the November 7, 2005 final rule (70 FR 67579) established the process of updating an official Part D e-prescribing standard with the recognition of ‘‘backward-compatible’’ versions of the official standard in instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification. In these instances, notice and comment rulemaking could be waived, and use of either the new or old version of the adopted standard would be considered compliant with the adopted standard upon the effective date of the newer version’s incorporation by reference in the **Federal Register**. This ‘‘Backward Compatible’’ version updating process allows for the standards’ updating/maintenance to correct technical errors, eliminate technical inconsistencies, and add optional functions that provide optional enhancements to the specified e-prescribing transaction standard. Since the adoption of the NCPDP Formulary and Benefits 1.0 standard in the Part D e-

prescribing program, NCPDP has updated its Formulary and Benefits standard. Changes were based upon industry feedback and business needs and ranged in complexity from creating whole new fields or lists within the standard to simply changing a particular field designation from mandatory to optional. Each time a change is made to a standard it is given a new version number. The current version of the Formulary and Benefits standard is version 3.0.

One of the major improvements between version 1.0 and 3.0 involved the addition of Text message support for "Coverage and Copay Information," the addition of the "Text Message Type (A46-1S)" field and the addition of "Optional Prior Authorization Lists." Theses list were added for use in conveying prior authorization requirements.

Other improvements included conversion of certain elements from optional to mandatory. Version 3.0 also provides for "Formulary Status List Headers," which are fields that allow the sender to specify a default formulary status for non-listed drugs. Subsequent versions also allowed for the omission of "Formulary Status Detail" records when the non-listed formulary policies are used exclusively to convey the status of a drug on a formulary.

Changes to a standard may also involve removing fields that are not widely used in industry. The removed fields are often replaced by new fields that better serve the business needs of the industry. For example, the following items have been removed through the various updates that led up to version 3.0: "Classification List" and references to it (such as Drug Classification Information), "Coverage Information Detail – Medical Necessity (MN)," "Coverage Information Detail – Resource Link – Summary Level (RS)," and the Classification ID in the Cross Reference Detail.

In place of these deleted fields, the following fields were added or amended to ultimately result in Version 3.0: The "Formulary Status existing value 2" field was changed to "On Formulary/Non-Preferred," The following has been clarified from " The file load also enables

payers to specify a single coverage-related text message for each drug" field was changed to "A payer may send multiple quantity limits, step medications, text messages and resource links for the same drug."

We have reviewed Version 3.0, and based on our findings, we have determined that Formulary and Benefits 3.0 maintains full functionality of the official adopted Part D e-prescribing standard Formulary and Benefits 1.0, and would permit the successful communication of the applicable transaction with entities that continue to use Version 1.0.

While we would usually use the "backward compatible" waiver of notice and comment procedures that are described above to recognize Version 3.0 as a backward compatible version of the officially adopted Version 1.0, this would have to be done in an interim final rule with comment. As we cannot combine proposals and elements of a final rule in one rule, we are electing this one time to formally propose recognizing a subsequent standard as a backward compatible version of an adopted standard through full notice and comment rulemaking in order to avoid having to publish two rules contemporaneously. We therefore propose to recognize the use of either Version 1.0 or 3.0 as compliant with the adopted Version 1.0 effective 60 days after the publication of a final rule.

As noted above, according to the November 7, 2005 final rule (70 FR 67580), entities that voluntarily adopt later versions of standards that are recognized as backward compatible versions of the official Part D e-prescribing standard must still accommodate the earlier official Part D e-prescribing standard without modification. Therefore, as we are using full notice and comment in place of the backward compatible methodology in this one instance, we also propose to require users of 3.0 to support users who are still using Version 1.0 until such time as Version 1.0 is officially retired as a Part D e-prescribing standard and Version 3.0 is adopted as the official Part D e-prescribing standard.

To effectuate these proposals, we also propose to revise §423.160(b)(5) by placing the existing material in a new subsection (b)(5)(i), and creating a second new subsection ((b)(5)(ii)) to reflect the use of Version 3.0. as a backward compatible version of the official Part D e-prescribing standard [i from 60 days from the publishing of the final rule through October 31, 2013 We seek comment on this proposal as well.

. We also seek comment on timing and when to retire Version 1.0 as the official Part D e-prescribing standard, and the proposal to adopt Formulary and Benefit Version 3.0. as the official Part D e-prescribing standard.

c. Proposed Elimination of the Exemption for Non-Prescribing Providers (Long Term Care)

In our November 16, 2007 proposed rule (72 FR 64902 - 64906), we discussed the inability of NCPDP SCRIPT versions 5.0 and 8.1 to support the workflows and legal responsibilities in the long-term care setting, that is, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser (‘‘three-way prescribing communications’’ between facility, physician, and pharmacy). As such, such entities were provided with an exemption from the requirement to use the NCPDP SCRIPT standard in transmitting such prescriptions or prescription-related information. On July 1, 2010 we published an IFC (75 FR 38029) in which we conveyed that we would consider removing the LTC exemption when there was an NCPDP SCRIPT standard that could address the unique needs of long-term care settings. We noted that NCPDP SCRIPT Version 10.6 was available, and that we believed that it addressed the concerns of the LTC industry regarding their ability to successfully support their workflows when e-prescribing. We solicited comments on the impact and timing of adopting version 10.6 as the

official Part D e-prescribing standard and the removal of the long-term care facility exemption from the NCPDP SCIPT standard.

LTC enhancements were first made to the NCPDP SCRIPT version 10.2, and were subsequently further enhanced in subsequent versions of the SCRIPT Standard.

In a July 1, 2009 recommendation letter to the Secretary, (http://www.ncvhs.hhs.gov/090701lt.pdf) NCVHS recommended the adoption of Version 10.6, the retirement of Version 8.1 and the lifting of the current exemption at §423.160(a)(3)(iv) from the requirement to use the NCPDP SCRIPT standard for providers in long-term care settings. During the NCVHS testimony that preceded the recommendation letter, members of the industry testified that the changes that were present in NCPDP SCRIPT 10.6 created an environment where long-term care (LTC) facilities could carry out e-prescribing using NCPDP SCRIPT 10.6 if it were to be adopted as the official Part D e-prescribing standard. More information on the testimony given to, and the recommendations given by NCVHS, can be found at the NCVHS Website http://www.ncvhs.hhs.gov/.

We considered the recommendations of the industry and NCVHS and concluded that it would be appropriate to retire Version 8.1, adopt Version 10.6 and eliminate the LTC exemption from the NCPDP SCRIPT standard. Since the LTC industry currently is exempt from the requirement to use the NCPDP SCRIPT Version 8.1 standard, Medicare Part D e-prescribing operators, providers, and vendors have been utilizing proprietary e-prescribing solutions and interfaces in the form of electronic medication administration records and internet communications, which are likely not interoperable. As the use of Part D e-prescribing standards would promote our administrative priorities of promoting interoperability and harmonization among IT systems, we therefore propose to retire Version 8.1, adopt Version 10.6 and eliminate the current exemption at §423.160(a)(3)(iv) for entities transmitting prescriptions or prescription-

related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser.

We are soliciting comments on lifting the Long Term Care exemption, effective November 1, 2013 in conjunction with the effective date of NCPDP SCRIPT 10.6. We solicit comments regarding the impact of these proposed effective dates on industry and other interested stakeholders, and whether an earlier or later effective date should be adopted.

**IV. Technical Corrections**

A. Waiver of Deductible for Surgical Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test and Colorectal Cancer Screening Test Definition.

Section 4104(c) of the Affordable Care Act amended section 1833(b)(1) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic in the course of the procedure or visit. Specifically, section 1833(b)(1) of the Act waives the deductible for colorectal screening tests regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. To implement this statutory provision, we proposed that "all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be considered to be furnished in connection with, as a result of, and in the same clinical encounter as the screening test." After receiving public comment, this proposal was finalized in the CY 2011 final rule with comment period (75 FR 73431). However, we neglected to amend our regulations to reflect this policy.

When a screening test becomes a diagnostic service, practitioners are to append a modifier to the diagnostic procedure code that is reported instead of the HCPCS code for screening colonoscopy or screening flexible sigmoidoscopy or as a result of the barium enema. By use of this modifier, practitioners signal that the procedure meets the criteria for the deductible to be waived.

To reflect this policy in our regulations, we propose to amend §410.160 Part B annual deductible to include colorectal screening tests that become diagnostic services in the list of services for which the deductible does not apply. Specifically, we propose to add a new §410.160(b)(8) to read, "Beginning January 1, 2011, a surgical service furnished on the same

date as a planned colorectal cancer screening test as described in §410.37."

Section 103 of the BIPA amended section 1861(pp)(1)(C) of the Act to permit coverage of screening colonoscopies for individuals not at high risk for colorectal cancer who meet certain requirements. In order to conform our regulations to section 1861(pp)(1)(C) of the Act, we propose to modify §410.37(a)(1)(iii) to define "Screening colonoscopies" by removing the phrase "In the case of an individual at high risk for colorectal cancer" from this paragraph.

We also propose to delete paragraph (g)(1) from this section since Medicare no longer receives claims for dates of service between January 1, 1998 and June 30, 2001, making this paragraph obsolete. We also propose to redesignate paragraphs (g)(2) through (g)(4) and make technical changes to newly redesignated paragraph (g)(1) by replacing the reference to paragraph (g)(4) with a reference to newly redesignated paragraph (g)(3).

## V. 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):

A. ICRs Regarding Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§410.32)

Proposed §410.32(d)(2)(i) would require that the physician or qualified nonphysician practitioner (as defined in §410.32(a)(2)) who orders the service maintain documentation of medical necessity in the beneficiary's medical record. In addition, both the medical record and the laboratory requisition (or order) would be required to be signed by the physician or qualified nonphysician practitioner who orders the service. The burden associated with these requirements would be the time and effort necessary for a physician or qualified nonphysician practitioner to sign the medical record or laboratory requisition (or order). There would also be a recordkeeping

requirement associated with maintaining the documentation of medical necessity in the beneficiary medical record. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned information collection requirements would be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practices.

B. ICRs Regarding Durable Medical Equipment Scope and Conditions (§410.38(g))

In §410.38(g), we would require (as a condition of payment for certain covered items of DME) that a physician must have documented and communicated to the DME supplier that the physician or a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written.

We propose that when the face-to-face encounter is performed by a physician, the submission of the pertinent portion(s) of the beneficiary's medical record (portions containing sufficient information to document that the face-to-face encounter meets our requirements) would be considered sufficient and valid documentation of the face-to-face encounter when submitted to the supplier and made available to CMS or its agents upon request. While we believe that many of the practitioners addressed in this proposed rule are already conducting a needs assessment and evaluating or treating the beneficiary for conditions relevant to the covered item of DME, this proposed rule may require some changes in their procedures to ensure that their documentation fulfills Medicare's regulatory requirements. Suppliers should already be receiving written orders and documentation to support the appropriateness of certain items of DME.

To promote the authenticity and comprehensiveness of the written order and as part of

our efforts to reduce the risk of waste, fraud, and abuse, we propose that as a condition of payment a written order must include: (1) the beneficiaries' name; (2) the item of DME ordered; (3) prescribing practitioner NPI; (4) the signature of the prescribing practitioner; (5) the date of the order; (6) the diagnosis; and (7) necessary proper usage instructions, as applicable.

In order to determine costs associated with the impact we utilized the Bureau of Labor Statistics mean hourly rates for the professional, analyzed for the year that the original data was received. The hourly rate for a physician, including fringe benefits and overhead is estimated at $118 per hour. The hourly rate, including fringe benefits and overhead, for a NP, PA, CNS is estimated at $55 per hour. The hourly rate for administrative assistant, including fringe benefits and overhead, is estimated at $23 per hour.

Physicians are now required to document the face-to-face encounter if it was performed by a PA, NP, or CNS. In order to allow payment for this documentation, a G code is established for this service. There are approximately 10 million DME users and it was assumed that roughly 5 percent of face-to-face encounters are actually performed by these other provider types, thereby requiring documentation of the encounter. Therefore, it was assumed that about 500,000 of these documentation services would be billed. We estimate the time for a physician to review each one of these encounters that results in an order is 10 minutes. Therefore, we estimate that the physician documentation burden to review and document when a PA, NP or CNS performed the face-to-face encounter in year 1 would be nearly 83,333 hours and a total of 700,000 million hours over 5 years. The associated cost in year 1 is nearly $9.8 million and over 5 years has associated costs of nearly $82.6 million based on the growth rate of the Medicare population. The increase is slightly more than five-fold because the number of Medicare beneficiaries would increase over time.

**TABLE 78: Physician Time to Document Occurrence of a Face-to-Face Encounter**

| | Year 1 | 5 Years |
|---|---|---|
| Number of claims affected | 500,000 | 4,200,000 |
| Time for physician review of each claim | 10 min | 10 min |
| Total Time | 83,333 hours | 700,000 hours |
| Estimated Total Cost (Hours times $118) | $ 9,833,333 | $ 82,600,000 |

We assume it will take 3 minutes for a PA, NP, or CNS to prepare the medical record for the review of the face-to-face encounter. For the 500,000 orders used in the previous estimate, this creates a total of 25,000 hours at a cost of about $1.4 million in year 1 and nearly 210,000 hours over 5 years at a cost of nearly $11.6 million based on the growth rate of the Medicare population. Though consistent with previous estimates, we believe that using a PA, NP, or CNS hourly rate creates a high burden impact estimate since most of these tasks would more than likely be completed by administrative personnel. We welcome comments on the appropriateness of these estimates.

**TABLE 79: Physician Assistant, Nurse Practitioner or Clinical Nurse Specialist Time**

| | Year 1 | 5 Years |
|---|---|---|
| Number of claims affected | 500,000 | 4,200,000 |
| Time for PAs, NPs, or CNSs to gather and provide each claim | 3 min | 3 min |
| Total Time | 25,000 hours | 210,000 hours |
| Estimated Total Cost (Hours times $55) | $ 1,375,000.00 | 11,550,000 |

This proposed rule would create only a minimal change in the normal course of business activities in regards to recordkeeping. Although we believe the documentation of a needs assessment, evaluation, and or treatment of a beneficiary for a condition relevant to an item of DME is a common practice, it is possible that some practitioners may not be documenting the results of all encounters; and therefore, there may be additional impact for some practitioners.

This regulation requires that the supplier have access to the documentation of the face-to-face encounter, which is required when CMS conducts an audit. CMS already accounts for the

audit burden associated with the exchange of documentation for claims subject to prepayment review (approved under OCN 0938-0969). As a business practice we recognize that some suppliers may receive the documentation of the face-to-face for all applicable claims, voluntarily.

We believe that the requirements expressed in this proposed rule meet the utility and clarity standards. We welcome comment on this assumption and on ways to minimize the burden on affected parties. The proposed recordkeeping requirement in §410.38(g)(5) and the requirement to maintain and make the supplier's order/additional documentation available to CMS upon request is subject to the PRA, but we believe that these requirements are usual and customary business practices as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

C. ICRs Regarding Physician Quality Reporting System – Definitions (§414.90(b))

While §414.90(b) contains 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. All of the requirements and burden estimates are currently approved by OMB under OCN 0938-1083, 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.).

D. ICRs Regarding Physician Quality Reporting System – Use of Consensus-based Quality Measures (§ 414.90(e))

We are proposing to revise §414.90(e), redesignated as to broadly define our use of consensus-based quality measures. The current regulation at §414.90(e) states that we will publish a final list of measures every year. However, we are proposing measures for 2013 and beyond this year .

While §414.90(e) contains 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. All of the requirements and burden estimates are currently approved by OMB under OCN 0938-1083, 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.).

E. ICRs Regarding Physician Quality Reporting System – Requirements for the Incentive Payments (§ 414.90(g))

While §414.90(g) contains information collection requirements regarding the PQRS incentive payments, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions. All of the requirements and burden estimates are currently approved by OMB under OCN 0938-1083, 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.).

F. ICRs Regarding Physician Quality Reporting System – Requirements for the Payment Adjustments (§414.90)

While §414.90 contains information collection requirements regarding the PQRS payment adjustments, this rule would not revise any of the information collection requirements or burden estimates that are associated with those provisions, except for the proposed criteria for reporting via claims for the 2015 and 2016 PQRS payment adjustments and the provisions that would allow the administrative claims reporting option. Otherwise, all of the requirements and burden estimates are currently approved by OMB under OCN 0938-1083 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.).

With respect to the proposed reporting criteria for the 2015 and 2016 PQRS payment

adjustments using the claims-based reporting mechanism, we note below that we anticipate that approximately 320,000 eligible professionals would use the claims-based reporting mechanism for CYs 2013 and 2014. This is a difference of 120,000 from the 200,000 that participated in PQRS using the claims-based reporting mechanism in 2010. We believe that these 120,000 eligible professional would use the 2015 and 2016 PQRS payment adjustment claims-based payment adjustment criteria to meet the criteria for satisfactory reporting for the 2015 and 2016 payment adjustments.

We estimate the cost for an eligible professional and group practices to review the list of PQRS quality measures or measures group, identify the applicable measures or measures group for which they can report the necessary information, incorporate reporting of the selected measures or measures group into the office work flows, and select a PQRS reporting option to be approximately $200 per eligible professional ($40 per hour x 5 hours). Based on our experience with the Physician Voluntary Reporting Program PVRP, we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for a measure) on claims will ranges from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. At an average labor cost of $40/hour per practice, the cost associated with this burden would range from $0.17 in labor to about $8.00 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.67.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was 9. Since we are proposing to reduce the required reporting rate by over one-third to 50 percent, then for purposes

of this burden analysis we will assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional or eligible professional in a group practice associated with claims-based reporting would range from 4.5 minutes (0.25 minutes per measure x 3 measures x 6 cases per measure) to 180 minutes (12 minutes per measure x 3 measures x 6 cases per measure), with the burden to the median practice being 31.5 minutes (1.75 minutes per measure x 3 measures x 6 cases). We estimate the total annual reporting cost per eligible professional or eligible professional in a group practice associated with claims-based reporting would range from $3.06 ($0.17 per measure x 3 measures x 6 cases per measure) to $144.00 ($8.00 per measure x 3 measures x 6 cases per measure), with the cost to the median practice being $30.06 per eligible professional ($1.67 per measure x 3 measures x 6 cases per measure).

With respect to reporting using the administrative claims reporting option, we estimate that the burden associated with reporting using the administrative claims option is the time and effort associated with reporting. We note that the burden for eligible professionals and group practices using the administrative claims-based reporting mechanism

G. Summary of Annual Burden Estimates for Codified Requirements (Proposed)

**TABLE 80: Summary of Annual Burden Estimates**

| Regulation section(s) | OCN | Respondents | Responses | Burden per response (hr) | Total burden (hr) |
|---|---|---|---|---|---|
| 410.38(g) re: Physician | 0938-New | 500,000 | 500,000 | 10 min | 83,333 |

| | | | | | |
|---|---|---|---|---|---|
| 410.38(g) re: PA, NP, or CNS | 0938-New | 500,000 | 500,000 | 3 min | 25,000 |
| 414.90(h) | 0938-1083 | 120,000 | 120,000 (120,000 responses x 1 measure) | 0.5 (31.5 minutes – the median) | 60,000 |

H. Additional Information Collection Requirements

While this proposed rule would impose collection of information requirements that are set out in the regulatory text (see above), this rule also sets out information collection requirements that are set out only in the preamble. Following is a discussion of the preamble-specific information collections, some of which have already received OMB approval.

1. Part B Drug Payment

The discussion of average sales price (ASP) issues in section XXX of this proposed rule does not contain any new information collection requirements with respect to payment for Medicare Part B drugs and biologicals under the ASP methodology. Drug manufacturers are required to submit ASP data to us on a quarterly basis. The ASP reporting requirements are set forth in section 1927(b) of the Act. The burden associated with this requirement is the time and effort required by manufacturers of Medicare Part B drugs and biologicals to calculate, record, and submit the required data to CMS. All of the requirements and burden estimates are currently approved by OMB under OCN 0938-0921, 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.).

2. Physician Quality Reporting System (PQRS)

The preamble of this proposed rule discusses the background of the PQRS, provides information about the proposed measures and reporting mechanisms that would be available to eligible professionals and group practices who choose to participate in the 2013 and 2014 PQRS, and provides the proposed criteria for satisfactory reporting in CYs 2013 and 2014 (for the 2013

and 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustments).

a. Participation in the 2013 and 2014 PQRS

According to the 2010 Reporting Experience Report, a total of $391,635,495 in PQRS incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0 percent incentive (i.e., a bonus payment equal to 2.0 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional in the reporting period) for satisfactory reporting under PQRS. For 2013 and 2014, eligible professionals can earn a 0.5 percent incentive for satisfactory reporting, a reduction of 1.5 percent from 2010. Therefore, based on 2010, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in PQRS would rise to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014 respectively.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5 percent incentive reduction from 2.0 percent in 2010 to 0.5 percent in 2013 and 2014, we estimate that the average amount per eligible professional earning an incentive in 2013 and 2014 would be $539. Therefore, we estimate that we would distribute approximately $162 million ($539 x 300,000 eligible professionals) and $216 million ($539 x 400,000 eligible professionals) in incentive payments in 2013 and 2014, respectively. We believe these incentive payments will help offset the cost to eligible professionals participating in PQRS for the applicable year. Please note that, beginning 2015, incentive payments for satisfactory reporting in PQRS will cease and payment adjustments for not satisfactorily reporting will commence.

We note that the total burden associated with participating in PQRS is the time and effort associated with indicating intent to participate in PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- The requirements for reporting for PQRS 2013 and 2014 incentives and 2015 and 2016 payment adjustments would be established as proposed in this 2013 Medicare PFS proposed rule.
- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, that the eligible professional or group practice would report on 3 measures.
- With respect to labor costs, we believe that a billing clerk would handle the administrative duties associated with participating, while a computer analyst would 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.

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 x 5 hours).

c. Burden Estimate on Participation in the 2013 and 2014 PQRS via the Claims-based Reporting Mechanism – Individual Eligible Professionals

In 2010, approximately 200,000 of the roughly 245,000 eligible professionals (or 84 percent) of eligible professionals used the claims-based reporting mechanism. We believe that although the number of eligible professionals or group practices using the claims-based reporting mechanism will increase in CYs 2013 and 2014, we anticipate that the percentage of eligible professionals or group practices using the claims-based reporting mechanism will decrease slightly as eligible professionals and group practices transition towards using the EHR-based reporting mechanism. Therefore, although we estimate that the participation rate for PQRS will double from participation rates in 2010, we note that, although we believe the claims-based reporting mechanism will be the most widely used, the percentage of PQRS participants using the claims-based reporting mechanism will decrease as we anticipate that more eligible professionals would use the registry and EHR-based reporting mechanisms. For these reasons, we estimate that approximately 320,000 eligible professionals, whether participating individually or in a group practice, will participate in PQRS in CY 2014.

With respect to an eligible professional who participates 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 submit 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 3 measures would range from 0.75 minutes to 36 minutes. Using an average labor cost of $40/hour, we estimate that time cost of reporting for an eligible professional via claims will range from $0.50 (0.75 minutes x $40/hour) to $24.00 (36 minutes x $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 will report will 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 ($0.50/per reported case x 6 reported cases) $3.00 to ($24.00/reported case x 6 reported cases) $144.

We note that, for the 2015 and 2016 PQRS payment adjustments, we are proposing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) register as an administrative claims reporter for the applicable payment adjustment and (2) report quality measures data. With respect to registration, we believe it would take approximately 2 hours to register for to participate in PQRS as an administrative claims reporter.

Therefore, we estimate that the cost of undergoing the GPRO selection process will be ($16/hour x 2 hours) $32. With respect to reporting, we note that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submit. Rather, CMS would bear the burden of reporting with respect to selecting which measures to report. We note that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

d. Burden Estimate on Participation in the CYs 2013 and 2014 PQRS via the Registry-based or EHR-based Reporting Mechanism

In 2010, approximately 40,000 of the roughly 245,000 eligible professionals (or 16 percent) of eligible professionals used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using the registry based reporting mechanism will remain the same, as eligible professionals use registries for functions other than PQRS and therefore would obtain a registry solely for PQRS reporting by CY 2014. In 2010, only 14 of the roughly 245,000 eligible professionals (or >1 percent) of eligible professionals used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will increase as eligible professionals become more familiar with EHR products. In particular, we believe eligible professionals and group practices will transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 40,000 eligible professionals (4 percent), whether participating as an individual or part of a group practice, will use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participates in PQRS via a qualified registry, direct EHR product, or EHR data submission vendor 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 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, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified 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 Participation in the CYs 2013 and 2014 PQRS – Group Practices

Unlike eligible professionals who choose to report individually, we note that we are proposing 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 will be ($16/hour x 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 x 79 hours) $3,160.

Eligible professionals who wish to qualify for an additional 0.5 percent Maintenance of Certification Program incentive will need to "more frequently" than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for 2012 and successfully complete a qualified Maintenance of Certification Program practice assessment for the applicable year. Although we understand that there is a cost associated with participating in a Maintenance of Certification Board, we believe that most of the eligible professionals attempting to earn this additional incentive would already be enrolled in a Maintenance of Certification Board for reasons other than earning the additional Maintenance of Certification Program incentive. Therefore, the burden to earn this additional incentive will depend on what a certification board establishes as "more frequently" and the time needed to complete the practice assessment component. We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment would be spread out over time since a quality improvement component is often required. With respect to the practice assessment component, according to an informal poll conducted by ABMS in 2012, the time an individual spends to complete the practice assessment component of the Maintenance of Certification ranges from 8-12 hours.

f. Burden Estimate on Vendor Participation in the CYs 2013 and 2014 PQRS

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that registry and EHR vendor products incur costs associated with participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimate that approximately 50 additional registries would self-nominate to be considered a qualified registry for PQRS. With respect to qualified 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 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 estimate 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 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 registry approximately ($16.00/hour x 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 will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS quality measures data will be the time and effort associated with submitting this data. To submit quality measures data for the proposed PQRS program years, 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 since we are proposing not to continue to require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data, there is no burden associated with qualification of direct EHR products and EHR data submission vendor products. With respect to reporting quality measures data, we believe the burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional would need to submit to CMS will depend on the vendor's familiarity with PQRS and the vendor's system and programming capabilities. Since we believe that an EHR vendor would be submitting data for reasons other than reporting under PQRS, we believe there would be no additional burden for an EHR vendor to submit quality measures data for PQRS reporting.

g. Summary of Burden Estimates on Participation in the 2013 and 2014 PQRS - Eligible Professionals and Vendors

**TABLE 81: Estimated Costs for Reporting PQRS Quality Measures Data for Eligible Professionals**

| | **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 | 0.2 | 6 | 3 | $40 | $144 |
| Individual EP: Administrative Claims | 2 | 1 | N/A | $16 | $32 |
| 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 82: Estimated Costs to Vendors to Participate in PQRS**

| | **Estimated Hours** | **Hourly Rate** | **Total Cost** |
|---|---|---|---|
| Registry: Self-Nomination | 10 | $160 | $160 |
| EHR: Programming | 0 | $0 | 0 |

3. Electronic Prescribing (eRx) Incentive Program

The requirements for the eRx Incentive Program for 2012—2014 were established in the CY 2012 Medicare PFS final rule. Although we are making proposals related to the eRx Incentive Program in the CY 2013 Medicare PFS, these proposals have no additional burden or impact on the public. Therefore, this rule would not revise the requirements or burden estimates approved by OMB under OCN: 0938-1083.

4. Physician Quality Reporting System-Medicare EHR Incentive Pilot

The Physician Quality Reporting System-Medicare EHR Incentive Pilot is a Pilot that provides a method whereby an eligible professional participating in both PQRS and Medicare EHR Incentive Program may submit one set of data and satisfy the reporting requirements for both programs. We believe any burden or impact associated with the Pilot would be absorbed in the burden and impact estimates provided for PQRS (OCN: 0938-1083) and the EHR Incentive Program.

I. 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-P]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov.

**VI. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## VII. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA), the Affordable Care Act, and other statutory changes. This proposed rule also is necessary to make changes to Part B drug payment policy and other related 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, 2012), 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 $7.0 million to $34.5 million in any 1 year (for details see the SBA's Website at http://www.sba.gov/content/table-small-business-size-standards (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

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

For purposes of the RFA, physicians, NPPs, and suppliers including IDTFs are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of physicians 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 we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis for the remaining provisions and addresses comments received on these issues.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 2012, that threshold is approximately $139 million. This proposed rule would have no consequential spending effect 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 BN.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2012 with proposed payment rates for CY 2013 using CY 2011 Medicare utilization as the basis for the comparison. To the extent that there are year-to-year changes in the volume and mix of services furnished by physicians, the actual impact on total Medicare revenues will be different from those shown in Tables 83 (CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty) and 84 (CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty by Selected Proposal). The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different 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 85 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Tables 83 and 84 show the payment impact on PFS services. We note that these impacts do not include the effect of the January 2013 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 section 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. While the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to permanently reform the SGR methodology for Medicare PFS updates. We provide our most recent estimate of the SGR and physician update for CY 2013 on our website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/.

The following is an explanation of the information represented in Table 83:

● 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 2011 utilization and CY 2012 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 2013 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 2013 impact on total allowed charges of the changes in the PE RVUs.

- Column E (Combined Impact): This column shows the estimated CY 2013 combined impact on total allowed charges of all the changes in the previous columns.

**TABLE 83: CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty***

| (A) Specialty | (B) Allowed Charges (mil) | (C) Impact of Work and MP RVU Changes | (D) Impact of PE RVU Changes | (E) Combined Impact |
|---|---|---|---|---|
| TOTAL | $ 86,000 | 0% | 0% | 0% |
| 01-ALLERGY/ IMMUNOLOGY | $ 198 | -1% | 1% | 0% |
| 02-ANESTHESIOLOGY | $ 1,970 | -1% | -3% | -3% |
| 03-CARDIAC SURGERY | $ 366 | -1% | -2% | -2% |
| 04-CARDIOLOGY | $ 6,568 | -1% | -2% | -3% |
| 05-COLON AND RECTAL SURGERY | $ 153 | -1% | 1% | 1% |
| 06-CRITICAL CARE | $ 261 | -1% | 0% | 0% |
| 07-DERMATOLOGY | $ 3,008 | -1% | 0% | 0% |
| 08-EMERGENCY MEDICINE | $ 2,819 | -1% | 0% | -1% |
| 09-ENDOCRINOLOGY | $ 434 | -1% | 1% | 1% |
| 10-FAMILY PRACTICE | $ 5,879 | 3% | 4% | 7% |
| 11-GASTROENTEROLOGY | $ 1,885 | -1% | 0% | 0% |
| 12-GENERAL PRACTICE | $ 579 | -1% | 1% | 0% |
| 13-GENERAL SURGERY | $ 2,261 | -1% | 0% | 0% |
| 14-GERIATRICS | $ 217 | 1% | 3% | 4% |
| 15-HAND SURGERY | $ 134 | -1% | 0% | 0% |
| 16-HEMATOLOGY/ ONCOLOGY | $ 1,900 | -1% | 0% | -1% |
| 17-INFECTIOUS DISEASE | $ 623 | -1% | 1% | 0% |
| 18-INTERNAL MEDICINE | $ 11,058 | 2% | 3% | 5% |
| 19-INTERVENTIONAL PAIN MGMT | $ 534 | -1% | 0% | -1% |
| 20-INTERVENTIONAL RADIOLOGY | $ 203 | -1% | -2% | -3% |
| 21-MULTISPECIALTY CLINIC/OTHER PHY | $ 202 | -1% | -1% | -1% |
| 22-NEPHROLOGY | $ 2,065 | -1% | 0% | -1% |

| (A) Specialty | (B) Allowed Charges (mil) | (C) Impact of Work and MP RVU Changes | (D) Impact of PE RVU Changes | (E) Combined Impact |
|---|---|---|---|---|
| 23-NEUROLOGY | $ 1,601 | -1% | 2% | 1% |
| 24-NEUROSURGERY | $ 681 | -1% | 0% | -1% |
| 25-NUCLEAR MEDICINE | $ 49 | -1% | -3% | -3% |
| 27-OBSTETRICS/ GYNECOLOGY | $ 698 | -1% | 0% | 1% |
| 28-OPHTHALMOLOGY | $ 5,621 | -1% | 1% | 1% |
| 29-ORTHOPEDIC SURGERY | $ 3,622 | -1% | 0% | -1% |
| 30-OTOLARNGOLOGY | $ 1,070 | -1% | 1% | 0% |
| 31-PATHOLOGY | $ 1,185 | -1% | -1% | -2% |
| 32-PEDIATRICS | $ 64 | 2% | 3% | 5% |
| 33-PHYSICAL MEDICINE | $ 990 | -1% | 1% | 1% |
| 34-PLASTIC SURGERY | $ 351 | -1% | 0% | 0% |
| 35-PSYCHIATRY | $ 1,149 | -1% | 0% | 0% |
| 36-PULMONARY DISEASE | $ 1,691 | -1% | 1% | 0% |
| 37-RADIATION ONCOLOGY | $ 1,983 | -1% | -14% | -14% |
| 38-RADIOLOGY | $ 4,791 | -1% | -3% | -4% |
| 39-RHEUMATOLOGY | $ 545 | -1% | 0% | 0% |
| 40-THORACIC SURGERY | $ 340 | -1% | -1% | -2% |
| 41-UROLOGY | $ 1,909 | -1% | -1% | -2% |
| 42-VASCULAR SURGERY | $ 882 | -1% | -2% | -3% |
| 43-AUDIOLOGIST | $ 57 | -1% | -4% | -5% |
| 44-CHIROPRACTOR | $ 738 | -1% | 1% | 1% |
| 45-CLINICAL PSYCHOLOGIST | $ 567 | -1% | -2% | -3% |
| 46-CLINICAL SOCIAL WORKER | $ 400 | -1% | -2% | -3% |
| 47-DIAGNOSTIC TESTING FACILITY | $ 875 | -1% | -7% | -8% |
| 48-INDEPENDENT LABORATORY | $ 1,064 | -1% | -1% | -1% |
| 49-NURSE ANES / ANES ASST | $ 1,142 | -1% | -3% | -4% |
| 50-NURSE PRACTITIONER | $ 1,606 | 1% | 3% | 5% |
| 51-OPTOMETRY | $ 1,048 | -1% | 2% | 1% |
| 52-ORAL/MAXILLOFACIAL SURGERY | $ 44 | -1% | 1% | 0% |
| 53-PHYSICAL/OCCUPATIONAL THERAPY | $ 2,613 | -1% | 3% | 3% |
| 54-PHYSICIAN ASSISTANT | $ 1,219 | 1% | 2% | 3% |
| 55-PODIATRY | $ 1,898 | -1% | 2% | 1% |
| 56-PORTABLE X-RAY SUPPLIER | $ 104 | -1% | 2% | 2% |
| 57-RADIATION THERAPY CENTERS | $ 71 | -1% | -18% | -19% |
| 98-OTHER | $ 19 | -1% | 1% | 0% |

* Table 83 shows only the proposed payment policy impact on PFS services. We note that these impacts do not include the effects of the negative January 2013 conversion factor change under current law.

Table 84 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 84:

- 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 2011 utilization and CY 2012 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 Baseline (PPIS transition, Updated Claims Data, and All Other Factors)): This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs due to the final year of the PPIS transition, proposed multiple procedure payment reduction for the TC of cardiovascular and ophthalmology diagnostic tests furnished on the same day (section II.B.4. of this proposed rule), all other proposals that result in minimal redistribution of payments under the PFS, the use of CY 2011 claims data to model payment rates, and other factors.

- Column D (Updated Equipment Interest Rate Assumption): This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs resulting from our proposed update to the equipment interest rate assumption as discussed in section II.A.2.f. of this proposed rule.

- Column E (Primary Care and Care Coordination: Post - Discharge Transitional Care Management Services): This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from our proposed policy to pay for post-discharge transitional care management services in the 30 days following an inpatient hospital, outpatient observation or partial hospitalization, skilled nursing facility (SNF), or community mental health center (CMHC) discharge as discussed in section II.H.1. of this proposed rule. We

would expect a negative impact on all non-primary care specialties due to the application of a BN adjustment to reflect the discharge transitional care management policy.

- Column F (Input Changes for Certain Radiation Therapy Procedures): This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from our proposal to revise the procedure times for certain radiation therapy procedures discussed in section II.B.3.b. of this proposed rule.

- Column G (Cumulative Impact): This column shows the estimated CY 2013 combined impact on total allowed charges of all the proposed changes in the previous columns.

**TABLE 84: CY 2013 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty by Selected Proposal***

| (A) | (B) | (C) | (D) | (E) | (F) | (G) |
|---|---|---|---|---|---|---|
| **Specialty** | **Allowed Charges (mil)** | **Baseline (PPIS transition, new utilization and other factors)** | **Updated Equipment Interest Rate Assumption** | **Discharge Transition Care Manage-ment** | **Input Changes for Certain Radiation Therapy Procedures** | **Total (Cumulative Impact)** |
| TOTAL | $ 85,485 | 0% | 0% | 0% | 0% | 0% |
| 01-ALLERGY/ IMMUNOLOGY | $ 198 | 0% | 1% | -2% | 1% | 0% |
| 02-ANESTHESIOLOGY | $ 1,969 | -2% | 0% | -1% | 0% | -3% |
| 03-CARDIAC SURGERY | $ 366 | -1% | 0% | -1% | 0% | -2% |
| 04-CARDIOLOGY | $ 6,565 | -1% | 0% | -1% | 0% | -3% |
| 05-COLON AND RECTAL SURGERY | $ 153 | 1% | 0% | -1% | 0% | 1% |
| 06-CRITICAL CARE | $ 261 | 1% | 0% | -1% | 0% | 0% |
| 07-DERMATOLOGY | $ 3,008 | 0% | 1% | -2% | 0% | -1% |
| 08-EMERGENCY MEDICINE | $ 2,819 | 0% | 0% | -1% | 0% | -1% |
| 09-ENDOCRINOLOGY | $ 434 | 1% | 0% | -1% | 0% | 0% |
| 10-FAMILY PRACTICE | $ 5,872 | 2% | 0% | 5% | 0% | 7% |
| 11-GASTROENTEROLOGY | $ 1,885 | 1% | 0% | -1% | 0% | 0% |
| 12-GENERAL PRACTICE | $ 577 | 1% | 0% | -1% | 0% | 0% |
| 13-GENERAL SURGERY | $ 2,261 | 1% | 0% | -1% | 0% | 0% |
| 14-GERIATRICS | $ 217 | 2% | 0% | 2% | 0% | 4% |
| 15-HAND SURGERY | $ 134 | 1% | 0% | -1% | 0% | 0% |
| 16-HEMATOLOGY/ ONCOLOGY | $ 1,891 | 0% | 1% | -2% | 0% | -1% |
| 17-INFECTIOUS DISEASE | $ 623 | 2% | 0% | -1% | 0% | 1% |
| 18-INTERNAL MEDICINE | $ 11,049 | 1% | 0% | 3% | 0% | 5% |
| 19-INTERVENTIONAL PAIN MGMT | $ 533 | 0% | 0% | -1% | 0% | -1% |

| (A) | (B) | (C) | (D) | (E) | (F) | (G) |
|---|---|---|---|---|---|---|
| **Specialty** | **Allowed Charges (mil)** | **Baseline (PPIS transition, new utilization and other factors)** | **Updated Equipment Interest Rate Assumption** | **Discharge Transition Care Manage-ment** | **Input Changes for Certain Radiation Therapy Procedures** | **Total (Cumulative Impact)** |
| 20-INTERVENTIONAL RADIOLOGY | $ 202 | -2% | 0% | -1% | 0% | -3% |
| 21-MULTISPECIALTY CLINIC/OTHER PHY | $ 201 | -1% | 0% | -1% | 0% | -2% |
| 22-NEPHROLOGY | $ 2,064 | 0% | 0% | -1% | 0% | -1% |
| 23-NEUROLOGY | $ 1,596 | 2% | 0% | -1% | 0% | 1% |
| 24-NEUROSURGERY | $ 680 | 0% | 0% | -1% | 0% | -1% |
| 25-NUCLEAR MEDICINE | $ 48 | -2% | -1% | -1% | 0% | -4% |
| 27-OBSTETRICS/ GYNECOLOGY | $ 698 | 1% | 0% | -1% | 0% | 0% |
| 28-OPHTHALMOLOGY | $ 5,621 | 2% | 0% | -1% | 0% | 1% |
| 29-ORTHOPEDIC SURGERY | $ 3,609 | 0% | 0% | -1% | 0% | -1% |
| 30-OTOLARNGOLOGY | $ 1,069 | 1% | 1% | -1% | 0% | 0% |
| 31-PATHOLOGY | $ 1,185 | -1% | 0% | -1% | 0% | -2% |
| 32-PEDIATRICS | $ 64 | 1% | 0% | 3% | 0% | 5% |
| 33-PHYSICAL MEDICINE | $ 980 | 2% | 0% | -1% | 0% | 1% |
| 34-PLASTIC SURGERY | $ 351 | 1% | 0% | -1% | 0% | 0% |
| 35-PSYCHIATRY | $ 1,149 | 1% | 0% | -1% | 0% | 0% |
| 36-PULMONARY DISEASE | $ 1,691 | 1% | 0% | -1% | 0% | 0% |
| 37-RADIATION ONCOLOGY | $ 1,982 | -3% | -3% | -2% | -7% | -15% |
| 38-RADIOLOGY | $ 4,724 | -2% | -1% | -1% | 0% | -4% |
| 39-RHEUMATOLOGY | $ 544 | 0% | 1% | -2% | 0% | 0% |
| 40-THORACIC SURGERY | $ 340 | -1% | 0% | -1% | 0% | -2% |
| 41-UROLOGY | $ 1,905 | -1% | 0% | -1% | 0% | -2% |
| 42-VASCULAR SURGERY | $ 881 | -2% | 0% | -1% | 0% | -3% |
| 43-AUDIOLOGIST | $ 57 | -3% | 0% | -1% | 0% | -5% |
| 44-CHIROPRACTOR | $ 738 | 2% | 0% | -1% | 0% | 0% |
| 45-CLINICAL PSYCHOLOGIST | $ 567 | -2% | 0% | -1% | 0% | -3% |
| 46-CLINICAL SOCIAL WORKER | $ 400 | -2% | 0% | -1% | 0% | -3% |
| 47-DIAGNOSTIC TESTING FACILITY | $ 848 | -5% | -2% | -2% | 1% | -8% |
| 48-INDEPENDENT LABORATORY | $ 1,064 | -2% | 1% | -2% | 1% | -2% |
| 49-NURSE ANES / ANES ASST | $ 1,142 | -3% | 0% | -1% | 0% | -4% |
| 50-NURSE PRACTITIONER | $ 1,606 | 2% | 0% | 3% | 0% | 5% |
| 51-OPTOMETRY | $ 1,048 | 2% | 0% | -1% | 0% | 1% |
| 52-ORAL/MAXILLOFACIAL SURGERY | $ 44 | 1% | 1% | -1% | 0% | 0% |
| 53-PHYSICAL/OCCUPATIONAL THERAPY | $ 2,263 | 3% | 0% | -1% | 0% | 3% |
| 54-PHYSICIAN ASSISTANT | $ 1,219 | 1% | 0% | 2% | 0% | 3% |
| 55-PODIATRY | $ 1,897 | 2% | 1% | -2% | 0% | 1% |
| 56-PORTABLE X-RAY | $ 104 | 2% | 1% | -2% | 1% | 2% |

| (A) | (B) | (C) | (D) | (E) | (F) | (G) |
|---|---|---|---|---|---|---|
| **Specialty** | **Allowed Charges (mil)** | **Baseline (PPIS transition, new utilization and other factors)** | **Updated Equipment Interest Rate Assumption** | **Discharge Transition Care Manage-ment** | **Input Changes for Certain Radiation Therapy Procedures** | **Total (Cumulative Impact)** |
| SUPPLIER | | | | | | |
| 57-RADIATION THERAPY CENTERS | $ 71 | -4% | -5% | -2% | -8% | -19% |
| 98-OTHER | $ 19 | 1% | 0% | -1% | 0% | 0% |

*Table 84 shows only the proposed payment policy impact on PFS services. We note that these impacts do not include the effects of the negative January 2013 conversion factor change under current law

2. CY 2012 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to several factors. First, as discussed in section II.A.2. of this proposed rule, we are currently implementing the final year of the 4-year transition to new PE RVUs using the PPIS data that were adopted in the CY 2010 PFS final rule with comment period. The impacts of the final year of the transition are generally consistent with the impacts that would be expected based on the impacts displayed in the CY 2012 final rule with comment period. The second factor is the post-discharge transitional care management proposal, under which we would pay separately for care coordination in the 30 days following an inpatient hospital, outpatient hospital observation services or partial hospitalization, SNF, or CMHC discharge from the treating physician in the hospital to the beneficiary's primary physician in the community.

Table 83 also reflects updates to the proposed interest rate assumption used in the medical equipment calculation in the PE RVU methodology, the proposed multiple procedure payment reduction policy for the technical component of diagnostic cardiovascular and ophthalmological procedures, and proposed changes to the inputs for certain radiation therapy procedures.

Table 84 shows the same information as provided in Table 83, but rather than isolating

the policy impact on physician work, PE, and malpractice separately, Table 84 shows the impact of varied proposed policies on total RVUs.

b. Combined Impact

Column E of Table 83 and column G of Table 84 display the estimated CY 2013 combined impact on total allowed charges by specialty of all the proposed RVU and MPPR changes. These impacts range from an increase of 7 percent for family practice to a decrease of 19 percent for radiation therapy centers. Again, these impacts are estimated prior to the application of the negative CY 2013 Conversion Factor (CF) update applicable under the current statute.

Table 85 (Impact of Proposed Rule on CY 2013 Payment for Selected Procedures (Based on the March 2012 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 2013 payment rates with and without the effect of the CY 2013 negative PFS CF update for comparison purposes. We selected these procedures because they are the most commonly furnished by a broad spectrum of physician specialties. There are separate columns that show the change in the facility rates and the nonfacility rates. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this proposed rule.

**TABLE 85: Impact of Proposed Rule on CY 2013 Payment for Selected Procedures (Based on the March 2012 Preliminary Physician Update)***

| CPT/ HCPCS [1] | MOD | Short Descriptor | Facility | | | | | Nonfacility | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CY 2012[2] | CY 2013[3] (pre update) | % Change (pre update) | CY 2013 [4] (post update) | % Change (post update) | CY 2012 [2] | CY 2013[3] (pre update) | % Change (pre update) | CY 2013 [4] (post update) | % Change (post update) |
| 11721 | | Debride nail 6 or more | $25.19 | $24.37 | -3% | $17.79 | -29% | $43.57 | $44.00 | 1% | $32.12 | -26% |
| 17000 | | Destruct premalg lesion | $56.16 | $56.19 | 0% | $41.01 | -27% | $81.01 | $81.23 | 0% | $59.29 | -27% |
| 27130 | | Total hip arthroplasty | $1,445.58 | $1,433.42 | -1% | $1,046.26 | -28% | NA | NA | NA | NA | NA |
| 27244 | | Treat thigh fracture | $1,231.48 | $1,223.23 | -1% | $892.84 | -27% | NA | NA | NA | NA | NA |
| 27447 | | Total knee arthroplasty | $1,544.29 | $1,530.22 | -1% | $1,116.91 | -28% | NA | NA | NA | NA | NA |
| 33533 | | Cabg arterial single | $1,950.35 | $1,897.80 | -3% | $1,385.21 | -29% | NA | NA | NA | NA | NA |
| 35301 | | Rechanneling of artery | $1,112.35 | $1,085.81 | -2% | $792.54 | -29% | NA | NA | NA | NA | NA |
| 43239 | | Upper gi endoscopy biopsy | $174.61 | $172.62 | -1% | $126.00 | -28% | $351.61 | $348.96 | -1% | $254.71 | -28% |
| 66821 | | After cataract laser surgery | $307.70 | $315.79 | 3% | $230.50 | -25% | $326.08 | $334.07 | 2% | $243.84 | -25% |
| 66984 | | Cataract surg w/iol 1 stage | $760.74 | $775.43 | 2% | $565.99 | -26% | NA | NA | NA | NA | NA |
| 67210 | | Treatment of retinal lesion | $504.10 | $507.37 | 1% | $370.33 | -27% | $523.84 | $524.63 | 0% | $382.93 | -27% |
| 71010 | | Chest x-ray | NA | NA | NA | NA | NA | $23.83 | $23.02 | -3% | $16.80 | -29% |
| 71010 | 26 | Chest x-ray | $8.85 | $8.80 | -1% | $6.42 | -27% | $8.85 | $8.80 | -1% | $6.42 | -27% |
| 77056 | | Mammogram both breasts | NA | NA | NA | NA | NA | $112.32 | $110.68 | -1% | $80.79 | -28% |
| 77056 | 26 | Mammogram both breasts | $42.55 | $41.63 | -2% | $30.39 | -29% | $42.55 | $41.63 | -2% | $30.39 | -29% |
| 77057 | | Mammogram screening | NA | NA | NA | NA | NA | $81.35 | $78.86 | -3% | $57.56 | -29% |

| CPT/ HCPCS [1] | MOD | Short Descriptor | Facility | | | | | Nonfacility | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CY 2012[2] | CY 2013[3] (pre update) | % Change (pre update) | CY 2013 [4] (post update) | % Change (post update) | CY 2012 [2] | CY 2013[3] (pre update) | % Change (pre update) | CY 2013 [4] (post update) | % Change (post update) |
| 77057 | 26 | Mammogram screening | $34.38 | $33.51 | -3% | $24.46 | -29% | $34.38 | $33.51 | -3% | $24.46 | -29% |
| 77427 | | Radiation tx management x5 | $177.00 | $182.77 | 3% | $133.41 | -25% | $177.00 | $182.77 | 3% | $133.41 | -25% |
| 88305 | 26 | Tissue exam by pathologist | $36.08 | $35.20 | -2% | $25.69 | -29% | $36.08 | $35.20 | -2% | $25.69 | -29% |
| 90801 | | Psy dx interview | $119.81 | $116.10 | -3% | $84.74 | -29% | $152.49 | $150.62 | -1% | $109.94 | -28% |
| 90862 | | Medication management | $44.25 | $43.66 | -1% | $31.87 | -28% | $58.54 | $58.89 | 1% | $42.99 | -27% |
| 90935 | | Hemodialysis one evaluation | $72.84 | $70.74 | -3% | $51.63 | -29% | NA | NA | NA | NA | NA |
| 92012 | | Eye exam established pat | $51.40 | $52.46 | 2% | $38.29 | -25% | $82.71 | $84.62 | 2% | $61.76 | -25% |
| 92014 | | Eye exam & treatment | $78.29 | $79.20 | 1% | $57.81 | -26% | $119.81 | $122.53 | 2% | $89.43 | -25% |
| 92980 | | Insert intracoronary stent | $837.67 | $804.20 | -4% | $586.99 | -30% | NA | NA | NA | NA | NA |
| 93000 | | Electrocardiogram complete | NA | NA | NA | NA | NA | $19.06 | $17.94 | -6% | $13.09 | -31% |
| 93010 | | Electrocardiogram report | $8.51 | $8.12 | -5% | $5.93 | -30% | $8.51 | $8.12 | -5% | $5.93 | -30% |
| 93015 | | Cardiovascular stress test | NA | NA | NA | NA | NA | $88.50 | $83.94 | -5% | $61.27 | -31% |
| 93307 | 26 | Tte w/o doppler complete | $45.95 | $44.34 | -4% | $32.36 | -30% | $45.95 | $44.34 | -4% | $32.36 | -30% |
| 93458 | 26 | L hrt artery/ventricle angio | $315.87 | $315.12 | 0% | $230.00 | -27% | $315.87 | $315.12 | 0% | $230.00 | -27% |
| 98941 | | Chiropractic manipulation | $30.63 | $30.46 | -1% | $22.23 | -27% | $36.08 | $36.22 | 0% | $26.43 | -27% |
| 99203 | | Office/outpatient visit | $74.88 | $74.46 | -1% | $54.35 | -27% | $105.18 | $106.28 | 1% | $77.57 | -26% |

| CPT/ HCPCS [1] | MOD | Short Descriptor | Facility | | | | | Nonfacility | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CY 2012[2] | CY 2013[3] (pre update) | % Change (pre update) | CY 2013 [4] (post update) | % Change (post update) | CY 2012 [2] | CY 2013[3] (pre update) | % Change (pre update) | CY 2013 [4] (post update) | % Change (post update) |
| | | new | | | | | | | | | | |
| 99213 | | Office/outpatient visit est | $49.69 | $49.76 | 0% | $36.32 | -27% | $70.46 | $71.76 | 2% | $52.37 | -26% |
| 99214 | | Office/outpatient visit est | $76.24 | $76.49 | 0% | $55.83 | -27% | $104.16 | $105.26 | 1% | $76.83 | -26% |
| 99222 | | Initial hospital care | $133.09 | $133.70 | 0% | $97.58 | -27% | NA | NA | NA | NA | NA |
| 99223 | | Initial hospital care | $195.38 | $196.99 | 1% | $143.78 | -26% | NA | NA | NA | NA | NA |
| 99231 | | Subsequent hospital care | $38.12 | $37.91 | -1% | $27.67 | -27% | NA | NA | NA | NA | NA |
| 99232 | | Subsequent hospital care | $69.78 | $70.06 | 0% | $51.14 | -27% | NA | NA | NA | NA | NA |
| 99233 | | Subsequent hospital care | $100.07 | $100.53 | 0% | $73.37 | -27% | NA | NA | NA | NA | NA |
| 99236 | | Observ/hosp same date | $212.05 | $211.88 | 0% | $154.65 | -27% | NA | NA | NA | NA | NA |
| 99239 | | Hospital discharge day | $103.13 | $103.91 | 1% | $75.84 | -26% | NA | NA | NA | NA | NA |
| 99283 | | Emergency dept visit | $60.25 | $59.57 | -1% | $43.48 | -28% | NA | NA | NA | NA | NA |
| 99284 | | Emergency dept visit | $114.71 | $113.73 | -1% | $83.01 | -28% | NA | NA | NA | NA | NA |
| 99291 | | Critical care first hour | $217.16 | $216.62 | 0% | $158.11 | -27% | $267.20 | $268.75 | 1% | $196.16 | -27% |
| 99292 | | Critical care addl 30 min | $108.92 | $108.65 | 0% | $79.30 | -27% | $119.47 | $119.82 | 0% | $87.46 | -27% |
| 99348 | | Home visit est patient | NA | NA | NA | NA | NA | $82.03 | $81.57 | -1% | $59.54 | -27% |
| 99350 | | Home visit est patient | NA | NA | NA | NA | NA | $171.21 | $172.96 | 1% | $126.24 | -26% |
| G0008 | | Immunization admin | NA | NA | NA | NA | NA | $24.17 | $25.05 | 4% | $18.28 | -24% |

*The CY 2013 payment rates are likely to differ from those shown in 85, as the CY 2013 CF is not yet final.

1 CPT codes and descriptions are copyright 2012American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
2 Payments based on the 2012conversion factor of 34.0376
3 Payments based on the 2012 conversion factor of 34.0376, adjusted to 33.8572 to include the BN adjustment.
4 Payments based on the 2013conversion factor of 24.7124, which includes the BN 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 add several new codes 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 similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the proposed additions.

E. Effect of Proposed Definition of Certified Registered Nurse Anesthetists' (CRNA) Services

As discussed in section II.K.1. of this proposed rule, we propose to define "anesthesia and related care" as used in the statutory benefit category for CRNAs under section 1861(bb)(2) of the Act to include those services that are related to anesthesia and included within the state scope of practice for CRNAs in the state in which the services are furnished. CMS has been requested to clarify the definition with regard to chronic pain management services. Contractors have reached different conclusions as to whether the statutory definition of "anesthesia services and related care" encompasses the chronic pain management services delivered by CRNAs. Given variations in state scopes of practice, we expect that differences on whether CRNAs can bill Medicare directly for these services will continue to exist. In addition, current Medicare policies do not prohibit CRNAs from furnishing these services in states where the scope of practice allows them to do so, but only prohibit them from billing Medicare directly. As a result of these two factors, we do not expect a significant change in how many services are billed to Medicare and therefore, we estimate no significant budgetary impact from this proposed change.

F. Effects of Proposed Change to Ordering Requirements for Portable X-Ray Services Under the PFS

As discussed in section III.K.2. of this proposed rule, we are proposing to revise our current regulation that limits ordering of portable x-ray services to only a doctor of medicine or a

doctor of osteopathy to allow other physicians and nonphysician practitioners (acting within the scope of State law and their Medicare benefit) to order portable x-ray services. We estimate no significant impact on PFS expenditures from the proposed additions.

G. Geographic Practice Cost Indices (GPCIs)

As discussed in section II.E. of this proposed rule, we are required to review and revise the GPCIs at least every 3 years and phase in the adjustment over 2 years (if there has not been an adjustment in the past year). For CY 2013, we are not proposing any revisions related to the data or methodologies used to calculate the GPCIs. However, since the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2013 PFS, the proposed CY 2013 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in addendums D and E of this CY 2013 PFS proposed rule do not reflect the 1.0 work GPCI floor for CY 2013. As required by section 1848 (e)(1)(G) and section1848 (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 applicable in CY 2013.

H. Other Provisions of the Proposed Regulation

1. Ambulance Fee Schedule-

As discussed in section III.A. of this proposed rule, section 306 of the TPTCCA and section 3007 of the MCTRJCA 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, through CY 2012. As further discussed in section III.A. of this proposed rule, this legislation is self-implementing, and 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.

2. Part B Drug Payment: ASP Issues

As discussed in section III of this proposed rule, we are proposing to update the AMP-based price substitution policy that would allow Medicare to pay based off lower market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Our impact analysis is unchanged from last year (76 FR 73462): based on estimates published in various OIG reports cited in the CY 2012 PFS final rule with comment period (76 FR 73290-1), we believe that this proposal will generate minor savings for the Medicare program and its beneficiaries since any substituted prices would be for amounts less than the calculated 106 percent of the ASP.

Our policy clarification regarding Pharmacy Billing for Part B Drugs Administered Incident to a Physician's Services which is discussed in section III of this proposed rule states that only physicians and not pharmacies (or DME suppliers) are allowed to bill Medicare under Part B for drugs administered in physicians' offices. We do not believe that this clarification will significantly impact the quantity or payment amount for part B drugs that are administered through implanted DME and or the procedures used to refill such pumps.

3. Medicare Program; Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

a. Overall Impact

We estimate the overall economic impact of this provision on the health care sector to be a cost of $49.95 million in the first year and $285.2 million over 5 years. This overall impact is comprised of additional administrative paperwork costs to private sector providers; a slight increase in Medicare spending, consisting of additional costs and some offsetting savings; and additional opportunity and out-of-pocket costs to Medicare beneficiaries. We believe there are likely to be other benefits and cost savings result from the DME face-to-face requirement,

however, many of those benefits cannot be quantified. For instance, we expect to see savings in the form of reduced fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (note that not all improper payments are fraudulent). Our detailed cost and benefit analysis is explained below. We are specifically soliciting comment on the potential increased costs and benefits associated with this provision.

**TABLE 86: Overall Economic Impact to Health Sector (in millions)**

| | Year 1 | 5 Years |
|---|---|---|
| Private Sector (Paperwork Cost) | $11.2 | $94.2 |
| Net Medicare impact of additional visits and G code billings | $5 | $30 |
| Beneficiaries | $29. 75 | $161 |
| Total Economic Impact to Health Sector | $ 49.95 | $ 285.2 |

The definition of small entity in the RFA includes non-profit organizations. Most suppliers and providers are small entities as that term is used in the RFA. Likewise, the vast majority of physician and NP practices are considered small businesses according to the Small Business Administration's size standards with total revenues of $10 million or less in any 1 year. While the economic costs and benefits of this rule are substantial in the aggregate, the economic impacts on individual entities will be relatively small. We estimate that 90 to 95 percent of DME suppliers and practitioners who order DME are small entities under the RFA definition. Physicians and other professionals would receive extra payments for some of the costs imposed, and other costs (for example, for additional practitioner visits) would be reimbursed by Medicare under regular payment rules. The rationale behind requiring a face-to-face encounter is to reduce inappropriate claims from those DME suppliers who have been abusing or defrauding the program. The impact on these suppliers could be significant, however since the purpose of the statute and this regulation is to reduce abusive and fraudulent DME sales, we do not view the burden placed on those providers in the form of lost revenues as a condition that we must

mitigate. We believe that the effect on legitimate suppliers and practitioners would be minimal.

Anticipated Effects

b. Costs

(1) Private Sector Paperwork Costs

We believe that most practitioners are already seeing the beneficiary no more than 90 days prior to the written order or within 30 days after the order is written in certain circumstances. However this regulation potentially requires increased documentation.

Although we have no quantitative data for a specific dollar figure for the additional DME that may now be authorized in accordance with §410.38(g), nor can we determine if there would be cost avoidance and a reduction of unnecessary DME, we acknowledge the potential for this provision to surpass the economically significant threshold. We do not believe that this proposed rule would significantly affect the number of legitimate written orders for DME. However, we would expect a decline in fraudulent, wasteful and abusive orders, thereby causing a decrease in the amount paid for DME overall.

The covered items of DME as outlined in the M Pages, including the proposed list of Specified Covered Items, contains items that meet at least one of the criteria. The four criteria are as follows: (1) items that currently require a written order prior to delivery per instructions in our Program Integrity Manual; (2) items that cost more than $1,000; (3) items that we, based on our experience and recommendations from the DME MACs, believe are particularly susceptible to fraud, waste, and abuse; (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the HHS Office of Inspector General, the Government Accountability Office or other oversight entities. We are requesting comments on our criteria.

We also have estimated the number of different covered Medicare itemssubject to this proposed rule at approximately 164 HCPCS codes for items of DME. As new products enter the

market this number could increase, which could increase the impact. In addition, we propose a G-code to pay physicians' for documenting the encounter conducted by a PA, a NP, or a CNS.

We anticipate there would be an impact as a result of additional office visits for the face-to-face encounter and the additional time spent by physicians to document the face-to-face encounters with a beneficiary when it is furnished by a PA, a NP, or a CNS.

In our estimate of overall cost we include the estimates from section III, of this proposed rule (Collection of Information Requirements section). These are estimated at $11.2 million in year 1 and $ 94.2 million over 5 years. These are driven by the physician documenting face-to-face encounters with a beneficiary when it is furnished by a PA, a NP, or a CNS, including the time to communicate the practitioners findings to physicians so they can complete the necessary documentation.

**TABLE 87: Private Sector Paperwork Costs**

| | **Year 1 (in millions)** | **5 Years (in millions)** |
|---|---|---|
| Physician time to document occurrence of a face-to-face encounter cost | $9.8 | $82.6 |
| PA, NP, or CNS costs | $1.4 | $11.6 |
| Total Cost | $11.2 | $94.2 |

(2) Medicare Costs

Medicare would incur additional costs associated with this proposed rule related to additional face-to-face encounters in the form of office visits, and additional payment for time spent documenting the face-to-face encounter if furnished by the PA, NP or CNS and not by the physician directly. Subsequently, a G-Code is being created to allow Medicare payment to physicians for documenting the face-to-face encounters that are furnished by a PA, NP, and CNS, and is included in this proposed rule.

From a programmatic standpoint we believe that there would be 750,000 additional office visits billed and 500,000 G code claims for the documentation. It is difficult to determine how

many PAs, NPs or CNSs wrote orders for covered items of DME, and while we lack exact empirical data, in order to provide an estimate, we assumed that 5 percent of the orders for covered items of DME were written by a PA, NP or CNS. For the purpose of this estimate we assume that each order requires a separate face-to-face encounter, recognizing fully that the estimate might be inflated.

While we believe that currently the majority of practitioners evaluate beneficiaries before ordering DME, some may not, and therefore, a certain number of beneficiaries would be required to have a new visit in order to fulfill the face-to-face encounter requirement. Actuarial estimates indicate approximately 5 percent of those obtaining covered items of DME in a given year did not see a practitioner in the 90 days preceding the order or in the 30 days after the order was written. We estimate that 500,000 beneficiaries would not see their practitioners in the 90 days prior to the written order for the covered item or in the 30 days after the order is written. We assume that 1.5 visits per year per affected beneficiary would be required to cover the DME services that currently fail to meet the face- to- face requirement. The range would be about one to three; possibly less than one if many beneficiaries choose not to meet the requirement or reschedule services. DME claims for beneficiaries who failed to meet the physician contact requirements averaged 3 line items per beneficiary. However, about 40 percent of these line items occur on the same date and so probably refer to the same event and could be authorized during a single visit. Some additional coordination is probable for DME purchases within a narrow time frame. To estimate the impact of the additional office visits we assumed 750,000 additional office visits (1.5 visits * 500,000 beneficiaries). We also assumed that the average cost for these office visits is around $65, which is consistent with a mid-level office visit under the PFS. This represents the total amount that the practitioners would receive, either from Medicare or the beneficiary, who is responsible for the 20 percent coinsurance.

Physicians are now required to document the face-to-face encounter if it was furnished by a PA, NP, or CNS. In order to allow payment for this documentation, a G code is established for this service. There are approximately 10 million DME users and it was assumed that roughly 5 percent of face-to-face encounters are actually furnished by these other practitioner types, thereby requiring documentation of the encounter. Therefore, it was assumed that about 500,000 of these documentation services would be billed. We cannot predict with any certainty the cost of this new service, but believe that $15 is a reasonable estimate. This represents the total amount that the physician would receive, either from Medicare or the beneficiary, who is responsible for the 20 percent coinsurance.

Therefore the estimated gross cost is estimated to be $45 million in year 1 and $250 million over 5 years; note that there are also savings to Medicare that must be netted against the cost of additional practitioner office visits, which are described later in the Benefits section. There is a high degree of uncertainty surrounding this estimate because it is difficult to predict how physicians and beneficiaries would respond to the new requirement.

This provision would assist in providing better documentation which may help to lower the error rate and thus reduce improper payments, including those stemming from waste, fraud and abuse. Since there is a large amount of potential variation in the amount of time that a face-to-face encounter may take for an item of DME, as a proxy our estimate is based on the amount of time needed for a mid-level visit to evaluate a beneficiary (E&M code 99213). The time allotted for this visit to furnish the face-to-face evaluation under a 99213 is 15 minutes. We welcome comments as to the appropriateness of E&M Code 99213 as a proxy measure of time required for a face-to-face encounter.

Based on actual data, projecting these historical patterns in light of the draft regulation is not straight-forward. Some line items may be bundled (perhaps because they are used together).

Beneficiaries may also change their behavior in response to the regulation. For example, beneficiaries would be required to visit a physician in order for Medicare to pay for a new piece of equipment may substitute this visit for a later visit that would have been for a routine service. In this situation, the overall number of visits would not increase. Moreover, some beneficiaries may choose not to pursue the DME item at that time. On the other hand, the proposed rule points out that some of the encounters reported on the practitioner claim now may not qualify to support the need for the item of DME. We assume that beneficiaries would decide not to schedule 10 percent of the additional visits required as a result of not needing the DME item and that some would substitute a required service for a later planned visit.

**TABLE 88: Medicare 5-Year Costs for Additional Face-to-Face Visits and G Code Billings**

| 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|
| $45 | $45 | $50 | $50 | $60 |

*These costs represent 80 percent of the allowed charges for the additional visits and the new G codes.

The requirement for a face-to-face encounter with a beneficiary in a certain time period as a condition of payment for DME is a new statutory requirement. It is not subject to the physician fee schedule budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. However, by regulation, we are proposing to make an additional payment through a new G-code for physician work documenting the face-to-face encounters that are performed by a PA, NP, and CNS. This additional regulatory spending is subject to the physician fee schedule budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act.

(c) Beneficiary Cost Impact

From a programmatic standpoint, approximately 5 percent of those obtaining covered items of DME in that year did not see a practitioner in the 90 days preceding the order or in the 30 days after the order was written. We estimate that 500,000 beneficiaries would not see their practitioners in the 90 days prior to the written order for the covered item or in the 30 days after

the order is written. As mentioned above, we assume that 1.5 visits per year per affected beneficiary would be required to cover the DME services that currently fail to meet the face to face requirement. The range would be about one to three; possibly less than one if many beneficiaries choose not to meet the requirement or reschedule services. DME claims for beneficiaries who failed to meet the physician contact requirements averaged 3 line items per beneficiary. However, about 40 percent of these line items occur on the same date and so probably refer to the same event and could be authorized during a single visit. Some additional coordination is probable for DME purchases within a narrow time frame**.** There are effects on travel time and cost for these beneficiaries. If it takes a beneficiary 1.25 hours to go to a practitioner, the total estimate is approximately 937,500 hours of time for this proposed rule. We assume that an average trip requires one hour and 15 minutes (45 minutes of round trip travel time and 30 minutes in the doctor's office—half for waiting and half for time with the staff). As a proxy we use $20 to estimate the cost per hour including loss of leisure time and travel cost for a beneficiary to see a practitioner. This is consistent with previous estimates of beneficiary leisure time as proposed in the May 4, 2011 proposed rule entitled "Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Medicare & Medicaid Participating Providers and Suppliers" 76 FR 25469. This creates an economic cost of nearly $18.75 million in year 1. Over 5 years this cost could reach $105 million. There will be additional out of pocket expenses at the 20 percent Medicare Part B coinsurance. We estimated this cost to be $10 million in year 1 and $56 million over 5 years.

**TABLE 89: Beneficiary Cost Impact Resulting from Additional Face-to-Face Visits to Obtain DME Services**

| | **Year 1** | **5 Years** |
|---|---|---|
| Total beneficiaries visits impacted | 750,000 | 4.2 million |
| Time per beneficiary | 1.25 hours | 1.25 hours |
| Total Time | 937,500 | 5.25 million |
| Beneficiary Time Cost ($20) | $18. 75 million | $105 million |

| | **Year 1** | **5 Years** |
|---|---|---|
| Out of Pocket Expense | $10 million | $56 million |
| **Estimated Total Beneficiary Cost Impact** | **$29. 75 million** | **$161 million** |

* These costs represent 20 percent of the allowed charges for the additional visits and the new G codes.

b. Benefits

There would be quantifiable benefits from an expected reduction in Medicare DME services provided. In addition, we anticipate additional, qualitative benefits from a decrease in waste, fraud, and abuse, which would decrease the number of services. Further, requiring that there be a face-to-face evaluation of the beneficiary helps ensure appropriate orders based on the individual's medical condition, which increases the quality of care that the beneficiary receives. It is difficult to measure how much waste, fraud, and abuse will be prevented as a result of this proposed rule since it is impossible to determine what would have happened in the absence of the proposed rule. This provision is expected to improve physician's documentation of DME, and therefore, will help reduce improper payments and move the agency towards its strategic goal to reduce the Medicare fee-for-service error rate for DME items which has a higher error rate than other Medicare services. The Comprehensive Error Rate Testing (CERT) program error rate for DME is high. Fraud is an improper payment, but not all improper payments are fraud.

Therefore, creating a measure of how much this proposed rule would save in terms of a reduction in waste, fraud and abuse is not possible. With that stated, in 2009 Medicare paid $1.7 billion for DME items covered by this proposed rule, and we estimate that $1.9 billion will be paid for covered items in 2012, and $9.9 billion over 5 years. Preventing waste, fraud and abuse by changing behavior that results in just a small percentage reduction in inappropriate or unnecessary ordering of DME services will generate Medicare savings. This is an area where savings can be found through increased oversight, such as this regulation proposes. We believe that the cost of the visits will be offset by the savings produced by this provision.

We project Medicare savings from reduced DME services; these savings partially offset the costs of additional physician office visits and documentation payments described earlier in the impact analysis. The year-to-year Medicare savings from reduced DME services is as follows:

**TABLE 90: Year-to-Year Medicare Savings from Reduced DME Services**

| | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| DME savings | -$40 | -$40 | -$45 | -$45 | -$50 |

Based on an analysis of 2007 DME claims, approximately 2 percent of total DME spending was for those beneficiaries who had little contact with their physician during the year. For this subset of spending we assumed that there would be a 20 percent reduction in spending due to the face-to- face requirement. We found similar reductions in DME expenditures among managed care enrollees compared to fee for service (FFS) beneficiaries in the Medical Expenditure Panel Survey. This assumption is fairly speculative but we think it is modest compared to the estimates of fraud and abuse reported elsewhere. The savings occurs because some beneficiaries will not choose to go to the physician to authorize the DME item, some physicians will not order the items that would otherwise have been provided in the absence of the regulation, and some suppliers will not be able to achieve a payment that might have occurred through an unnecessary sale or outright fraud.

The overall net impact to Medicare of the DME face-to-face encounter policy is $5 million in the first year and $30 million over the first 5 years.

This regulation produces an extra benefit that is difficult to quantify, but is an extremely positive one in terms of greater practitioner involvement. By increasing practitioner interactions with beneficiaries before ordering DME, beneficiaries would receive more appropriate DME and benefiting from higher quality care. Beneficiaries would also benefit from reduced out-of-

pockets costs by not having to pay for unnecessary DME. This accomplishes the objective of achieving greater practitioner accountability noted in the provisions of and the amendments made by section 6407 and other sections of the Affordable Care Act. We welcome public comment on the benefits of the DME face-to-face requirement, including any data that could help quantify the expected reduction in fraud, improper payments, or improved beneficiary quality of care.

Alternatives Considered

In this proposed rule, we consider a variety of options and have sought comments on these options in other sections of this proposed rule. We expect public comment on the way in which the supplier should be notified that a face-to-face has occurred wanting to limit the potential burden. We proposed several options for the physician documentation of a face-to-face encounter furnished by that physician. We believe just submitting the medical record for the applicable date of service would create the least cost while still producing the desired benefits. In this proposed rule we have also set forth different options of what physician documentation of a face-to-face encounter furnished by a PA, NP or CNS could look like, in the hope of receiving comments on determining the method that will create the least potential burden.

There are also options to change the list of covered DME, either by expanding it to cover more items or by minimizing it to cover fewer items with low unit costs. We welcome comment on our selection criteria.

Finally, there are other possible periods of time that could be set as the window within which face-to-face encounters must occur. We believe that the consistency with the home health rule benefits providers of services and suppliers, and beneficiaries but welcome comment on this proposal.

4. Non-Random Prepayment Review

We estimate no significant budgetary impact. We believe that the overall costs for most providers and suppliers would remain the same unless they are subject to non-random prepayment complex medical review for an extended period of time.

5. Ambulance Coverage-Physician Certification Statement

We estimate no significant budgetary impact.

6. Physician Compare Website

Section IV.N.2. of this proposed rule discusses the background of the Physician Compare Website. As described in section IV.N.2. of this proposed rule, we propose to develop aspects of the Physician Compare Website in stages. In the first stage, which was completed in 2011, we posted the names of those eligible professionals who satisfactorily participated in the 2009 Physician Quality Reporting System. The second phase of the plan, which was completed in 2012, included posting the names of eligible professionals who were successful electronic prescribers under the 2009 eRx Incentive Program, as well as eligible professionals (EPs) who participate in the EHR Incentive Program. The next phase of the plan includes posting of performance information with respect to the 2012 Physician Quality Reporting System GPRO measures which will be completed no sooner than 2013.

We are proposing to include performance information for the 2013 Physician Quality Reporting System GPRO web interface measures data no sooner than 2014, in addition to 2013 patient experience data for group practices participating in the 2013 Physician Quality Reporting System GPRO. As reporting of physician performance rates and patient experience data on the Physician Compare Website will be performed directly by us using the data that we collect under the 2012 Physician Quality Reporting System GPRO and other data collection methods, we do not anticipate any notable impact on eligible professionals with respect to the posting of information on the Physician Compare Website.

7. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

According to the 2010 Reporting Experience Report, a total of $391,635,495 in Physician Quality Reporting System incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0 percent incentive (i.e., a bonus payment equal to 2.0 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 under the Physician Quality Reporting System. For 2013 and 2014, eligible professionals can earn a 0.5 percent incentive for satisfactory reporting, a reduction of 1.5 percent from 2010. Therefore, based on 2010,which is the latest year in which PQRS has full participation data, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the Physician Quality Reporting System would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5 percent incentive reduction from 2.0 percent in 2010 to 0.5 percent in 2013 and 2014, we estimate that the average amount per eligible professional earning an incentive in 2013 and 2014 would be $539. Therefore, we estimate that the Physician Quality Reporting System would distribute approximately $162 million ($539 x 300,000 eligible professionals) and $216 million ($539 x 400,000 eligible professionals) in incentive payments in 2013 and 2014, respectively. We believe these incentive payments will help offset the cost to eligible professionals for participating in the Physician Quality Reporting System for the

applicable year. Please note that, beginning 2015, incentive payments for satisfactory reporting in the Physician Quality Reporting System will cease and payment adjustments for not satisfactory reporting will commence.

We note that the total burden associated with participating in the Physician Quality Reporting System is the time and effort associated with indicating intent to participate in the Physician Quality Reporting System, if applicable, and submitting Physician Quality Reporting System quality measures data. When establishing these burden estimates, we assume the following:

- The requirements for reporting for the Physician Quality Reporting System 2013 and 2014 incentives and payment adjustments for 2015 and beyond would be established as proposed in this 2013 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 report on 3 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality

Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System would be approximately $80 ($16/hour x 5 hours).

With respect to an eligible professional who participates in the Physician Quality Reporting System 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 Physician Quality Reporting System 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 3 measures would range from 0.75 minutes to 36 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 $0.50 (0.75 minutes x $40/hour) to $24.00 (36 minutes x $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 ($0.50/per reported case x 6 reported cases) $3.00 to ($24.00/reported case x 6 reported cases) $144.

We note that, for the 2015 and 2016 PQRS payment adjustments, we are proposing an administrative claims reporting option for eligible professionals and group practices. The burden associated with reporting using the administrative claims reporting option is the time and effort associated with using this option. To submit quality measures data for PQRS using the administrative claims reporting option, an eligible professional or group practice would need to (1) register as an administrative claims reporter for the applicable payment adjustment and (2) report quality measures data. With respect to registration, we believe it would take approximately 2 hours to register for to participate in PQRS as an administrative claims reporter. Therefore, we estimate that the cost of undergoing the GPRO selection process will be ($16/hour x 2 hours) $32. With respect to reporting, we note that any burden associated with reporting would be negligible, as an eligible professional or group practice would not be required to attach reporting G-codes on the claims they submit. Rather, CMS would bear the burden of reporting with respect to selecting which measures to report. We note that there would be no additional burden on the eligible professional or group practice to submit these claims, as the eligible professional or group practice would have already submitted these claims for reimbursement purposes.

With respect to an eligible professional or group practice who participates in the Physician Quality Reporting System via a qualified registry, direct EHR product, or EHR data submission vendor product, we believe there would be little to no burden associated for an eligible professional to report Physician Quality Reporting System 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, or EHR data submission vendor, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, or EHR data submission vendor product solely for the purpose of reporting Physician Quality Reporting System 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.

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 Physician Quality Reporting System as a group practice. The total burden for group practices who submit Physician Quality Reporting System 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 Physician Quality Reporting System, a group practice would need to (1) be selected to participate in the Physician Quality Reporting System GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the Physician Quality Reporting System as a GPRO, we believe it would take approximately 6 hours – including 2 hours to decode to participate in the Physician Quality Reporting System 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 Physician Quality Reporting System GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process would be ($16/hour x 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 Physician Quality Reporting System quality measures data for the proposed reporting options in an applicable year would be ($40/hour x 79 hours) $3,160.

Eligible professionals who wish to quality for an additional 0.5% Maintenance of Certification Program incentive must "more frequently" than is required to qualify for or maintain board certification status participate in a qualified Maintenance of Certification Program for 2013 and/or 2014 and successfully complete a qualified Maintenance of Certification Program practice assessment for the applicable year. Although we understand that there is a cost associated with participating in a Maintenance of Certification Board, we believe that most of the eligible professionals attempting to earn this additional incentive would already be enrolled in a Maintenance of Certification board for reasons other than earning the additional Maintenance of Certification Program incentive. Therefore, the burden to earn this additional incentive would depend on what a certification board establishes as "more frequently" and the time needed to complete the practice assessment component. We expect that the amount of time needed to complete a qualified Maintenance of Certification Program practice assessment would be spread out over time since a quality improvement component is often required. With respect to the practice assessment component, according to an informal poll conducted by ABMS in

2012, the time an individual spends to complete the practice assessment component of the Maintenance of Certification ranges from 8-12 hours.

Aside from the burden of eligible professionals and group practices participating in the Physician Quality Reporting System, we believe that registry, direct EHR, and EHR data submission vendor products incur costs associated with participating in the Physician Quality Reporting System.

With respect to qualified registries, the total burden for qualified registries who submit Physician Quality Reporting System 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 Physician Quality Reporting System, 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 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 Physician Quality Reporting System quality measures data. Therefore, we estimate that it would cost a registry approximately ($16.00/hour x 10 hours) $160 to become qualified to submit Physician Quality Reporting System 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 Physician Quality Reporting System. Therefore, we believe there would be little to no additional burden associated with reporting Physician Quality Reporting System 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 Physician Quality Reporting System.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit Physician Quality Reporting System 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 Physician Quality Reporting System, 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 Physician Quality Reporting System quality measures data. With respect to reporting quality measures data, we believe the burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional must submit to CMS would depend on the vendor's familiarity with the Physician Quality Reporting System and the vendor's system and programming capabilities. We believe it would take a vendor approximately 40 hours (for experienced vendors) to 200 hours (for first-time vendor participants) to submit Physician Quality Reporting System quality measures data. Therefore, we estimate that it would cost an EHR vendor ($40/hour x 40 hours) $1,600 to $8,000 to submit Physician Quality Reporting System quality measures data for its eligible professionals.

**TABLE 91: Estimated Costs for Reporting Physician Quality Reporting System Quality Measures Data for Eligible Professionals**

| | Estimated Hours | Estimated Cases | Number of Measures | Hourly Rate | Total Cost |
|---|---|---|---|---|---|
| Individual Eligible Professional | 5.0 | 1 | N/A | $16 | $80 |

| | Estimated Hours | Estimated Cases | Number of Measures | Hourly Rate | Total Cost |
|---|---|---|---|---|---|
| (EP): Preparation | | | | | |
| Individual EP: Claims | 0.2 | 6 | 3 | $40 | $144 |
| Individual EP: Administrative Claims | 2 | 1 | N/A | $16 | $32 |
| 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 92: Estimated Costs to Vendors to Participate in the Physician Quality Reporting System**

| | Estimated Hours | Hourly Rate | Total Cost |
|---|---|---|---|
| Registry: Self-Nomination | 10 | $40 | $400 |
| EHR: Programming | 40-200 | $40 | $1,600 - $1,800 |

8. Electronic Prescribing (eRx) Incentive Program

Please note that the requirements for becoming a successful electronic prescriber for the 2013 incentive and 2014 payment adjustment were established in the CY 2012 MPFS final rule with comment period. The proposed provisions contained in this CY 2013 MPFS proposed rule would make additional changes to the requirements for the 2013 incentive and 2014 payment adjustment for group practices. Specifically, CMS is proposing to add a new criterion for being a successful electronic prescriber for the 2013 incentive and 2014 payment adjustments for group practices of 2-24 eligible professionals given that CMS is proposing to modify the definition of group practice. However, we note that any additional impact a result of this proposal would be minimal, as it is our understanding the eligible professionals who would use this new reporting option are already participating in the eRx Incentive Program as individual eligible professionals.

For the reasons stated, the proposals would have no additional impact other than the impact of the 2013 and 2014 payment adjustments described in the CY 2012 MPFS final rule with comment period.

9. 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 2013 MPFS proposed rule impose requirements that eligible professionals in group practices within accountable care organizations would need to satisfy for purposes of the PQRS payment adjustment under the Medicare Shared Savings Program as the proposals related to the ACOs for the PQRS payment adjustment mirror the requirements that were established for earning the PQRS incentives.

10. Medicare EHR Incentive Program

Please note that the requirements for reporting clinical quality measures (CQMs) to achieve meaningful use under Stage 1 for the EHR Incentive Program were established in a standalone final rule published on July 28, 2010 (75 FR 44544). The proposals contained in this CY 2013 MPFS proposed rule merely propose methods to report CQMs to meet the CQM objective for achieving meaningful use under Stage 1 for the EHR Incentive Program. Therefore, the impacts to the proposal we are making to extend the use of attestation and the Physician Quality Reporting System-Medicare EHR Incentive Pilot to report CQMs were absorbed in the impacts discussion published in the EHR Incentive Program final rule published on July 28, 2010.

11. Chiropractic Services Demonstration

As discussed in section III of this rule with comment period, 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 fourth 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 the PFS for all chiropractors in CY s 2010 through 2014. To implement this required BN adjustment, we are recouping $10 million in CY 2013 by reducing the payment amount under the PFS for the chiropractic CPT codes (that is, CPT codes 98940, 98941, and 98942) by approximately 2 percent.

11. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The proposed changes to the Physician Feedback Program in section IV.I. of this proposed rule would not impact CY 2013 physician payments under the PFS. However, we expect that our proposals to use the Physician Quality Reporting System (PQRS) quality measures in the Physician Feedback reports and in the value modifier to be implemented in CY 2015 may result in increased participation in the PQRS in CY 2013. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the PQRS to determine and understand how the value modifier could affect their payments.

12. Medicare Coverage of Hepatitis B Vaccine: Modification of high risk groups eligible for Medicare Part B coverage of Hepatitis B vaccine.

As discussed in section III of this proposed rule, section 1861(s)(10)(B) of the Act authorizes Medicare coverage of hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B, as determined by the Secretary under regulations. Our current regulations are established at 42 CFR §410.63. We are proposing to modify §410.63(a)(1) by adding persons diagnosed with diabetes mellitus to the high risk group. While it is estimated that approximately 23 percent of non-institutionalized Medicare beneficiaries are diagnosed with diabetes mellitus, it is unclear how many of these beneficiaries will obtain these services. Therefore, the estimated impact of adding persons

diagnosed with diabetes mellitus to the high risk group eligible for coverage of hepatitis B vaccine and its administration is unknown for CY 2013.

13. Existing Standards for E-prescribing under Medicare Part D and Identification and Lifting the LTC Exemption

The e-prescribing standard updates that are proposed in this section of the proposed rule imposes no new requirements as the burden in using the updated standards is anticipated to be the same as using the old standards. We believe that prescribers and dispensers that are now e-prescribing largely invested in the hardware, software, and connectivity necessary to e-prescribe. We do not anticipate that the retirement of NCPDP SCRIPT 8.1 in favor of NCPDP SCRIPT 10.6 will result in significant costs. We also believe the same holds true for the standard updates for NCPDP Formulary and Benefits 3.0. The backward compatible Formulary and Benefits 3.0 imposes no new requirements on entities that are already e-prescribing. Entities that choose to use Formulary and Benefits 3.0 would be doing so voluntarily.

The proposed removal of the LTC exception to the NCPDP SCRIPT standard would impose a small burden on the LTC industry. LTC entities who use and developed proprietary solutions may need to invest in software programming updates if they had not already incorporated the Part D e-prescribing standards in their solutions. It is reasonable to assume that a small number of proprietary solutions would have to modify their software in order to adhere to the adopted e-prescribing standards. Other cost may be incurred though staff training on the use of the e-prescribing standards and the use of an e-prescribing solution if adopted by a LTC facility. Additional training cost may involve prescribers and dispensers learning the new workflows that an electronic prescription may or may not require.

I. 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.

J. 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; creating a separate payment for post-discharge transitional care management services in the 30 days after a beneficiary has been discharged from an inpatient hospital admission, from outpatient observation services and partial hospitalization program,, from a SNF, or from a CMHC; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS for certain radiation therapy services; capital interest rate assumptions; multiple procedure payment reduction for ophthalmology and cardiovascular diagnostic tests; and revisions to payment for Part B drugs will have a positive impact and improve the quality and value of care furnished to Medicare beneficiaries.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as it 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 85, the CY 2012 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $105.18 which means that in CY 2012 a beneficiary would be responsible for 20 percent of this amount, or $21.04. Based on this proposed rule, using the current (CY 2012) CF of 34.0376, the CY 2013 national payment

amount in the nonfacility setting for CPT code 99203, as shown in Table 85, is $106.31, which means that, in CY 2013, the proposed beneficiary coinsurance for this service would be $21.26

K. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table 93 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this proposed rule. This estimate includes the estimated FY 2012 cash benefit impact associated with certain Affordable Care Act and MCTRJCA provisions, and the CY 2013 incurred benefit impact associated with the estimated CY 2013 PFS conversion factor update based on the Mid-Session Review of the FY 2013 President's Budget baseline.

**TABLE 93: Accounting Statement: Classification of Estimated Expenditures**

| CATEGORY | TRANSFERS |
|---|---|
| CY 2013 Annualized Monetized Transfers | Estimated decrease in expenditures of $23.5 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 2013 Annualized Monetized Transfers | Estimated increase in payment of 162 millions |
| From Whom To Whom? | Federal Government to eligible professionals participated in (Physician Quality Reporting System (PQRS) |

**TABLE 94: Accounting Statement:**
**Classification of Estimated Costs, Transfer, and Savings ($ In Millions)**

| CATEGORY | BENEFIT |
|---|---|
| Qualitative (unquantified) benefits of fraud, waste, and abuse prevented, and of improved quality of services to patients improved quality of services to patients | No precise estimate available |
| **CATEGORY** | **COST** |
| CY 2013 Annualized monetized costs of beneficiary travel time | $9.37 millions |
| **CATEGORY** | **TRANSFER** |
| CY 2013 Annualized Monetized Transfers of beneficiary cost coinsurance | $10 millions |
| From Whom To Whom? | Beneficiaries to Federal Government |
| **CATEGORY** | **TRANSFER** |
| CY 2013 Medicare face-to-face visit and G-code payments | $16.2 millions |
| From Whom To Whom? | Federal Government to DME providers |

L. 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 remainder 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 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

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

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, 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.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapters IV as set forth below:

**PART 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

1. 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.

2. Section 410.32 is amended by--

A. Revising paragraphs (b)(2)(iii) introductory text, (d)(2)(i), and (e).

B. Redesignating paragraphs (c)(2) and (c)(3) as paragraphs (c)(3) and (c)(4), respectively.

C. Adding new paragraph (c)(2)

The revisions and addition read as follows:

**§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.**

* * * * *

(b) * * *

(2) * * *

(iii) Diagnostic psychological and neuropsychological testing services when—

* * * * *

(c) * * *

(2) These services are ordered by a physician as provided in (a) or by a nonphysician practitioner as provided in (a)(2) of this section.

(d) * * *

(2) * * *

(i) Ordering the service. The physician or (qualified nonphysican practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

* * * * *

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

**§410.37 [Amended]**

3. Amend §410.37 by--

A. Revising paragraph (a)(1)(iii) by removing the phrase "In the case of an individual at high risk for colorectal cancer,".

B. Removing paragraph (g)(1).

C. Redesignating paragraphs (g)(2) through (g)(4) as paragraph (g)(1) through (g)(3), respectively.

D. In newly redesignated paragraph (g)(1), removing the reference "(g)(4)" and adding in its place the reference "(g)(3)".

4. Section 410.38 is amended by revising paragraph (g) to read as follows:

**§410.38 Durable medical equipment: Scope and conditions.**

* * * * *

(g)(1) Items requiring a written order. As a condition of payment, Specified Covered Items (as described in paragraph (g)(2) of this section) require a written order that meets the requirements in paragraphs (g)(3) and (4) of this section before delivery of the item.

(2) Specified covered items. (i) Specified Covered Items are items of durable medical equipment that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A

list of these items is updated annually in the **Federal Register**.

(ii) The list of Specified Covered Items includes the following:

(A) Any item described by a Healthcare Common Procedure Coding System (HCPCS) code for the following types of durable medical equipment:

(1) Transcutaneous electrical nerve stimulation (TENS) unit.

(2) Rollabout chair.

(3) Wheelchair accessories.

(4) Oxygen and respiratory equipment.

(5) Hospital beds and accessories.

(6) Traction-cervical.

(B) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling at or greater than $1,000.

(C) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

(iii) The list of specific covered items excludes the following:

(A) Any item that is no longer covered by Medicare.

(B) Any HCPCS code that is discontinued.

(3) Face-to-face encounter requirements. (i) For orders issued in accordance with paragraphs (g)(1) and (2) of this section, as a condition of payment for the Specified Covered Item, all of the following must occur:

(A) The physician must document and communicate to the DME supplier that the physician or a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a

face-to-face encounter with the beneficiary on the date of the written order or during either of the following:

(1) Up to 90 days before the date of the written order.

(2) Within 30 days after the date that the order is written.

(B) During the face-to-face encounter the physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must conduct a needs assessment, evaluate, or treat the beneficiary for the medical condition that supports the need for each covered item of DME ordered.

(C) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans or other information as it may be appropriate).

(i) For purposes of paragraph (g), a face-to-face encounter does not include DME items and services furnished from an "incident to" service.

(ii) For purposes of paragraph (g), a face-to-face beneficiary encounter may occur via telehealth in accordance with all of the following:

(A) Section 1834(m) of the Act.

(B)(1) Medicare telehealth regulations in §410.78 and §414.65 of this chapter; and

(2) Subject to the list of payable Medicare telehealth services established by the applicable PFS.

(4) Written order issuance requirements. Written orders issued in accordance with paragraphs (g)(1) and (2) of this section must include all of the following:

(i) Beneficiary's name.

(ii) Item of DME ordered.

(iii) Prescribing practitioner NPI.

(iv) Signature of the prescribing practitioner.

(v) The date of the order.

(vi) The beneficiary's diagnosis.

(vii) Necessary proper usage instructions, as applicable

(5) Supplier's order and documentation requirements. (i) A supplier must maintain the written order and the supporting documentation provided by the physician, physician assistant, nurse practitioner, or clinical nurse specialist and make them available to CMS upon request for 7 years from the date of service consistent with §424.516(f) of this chapter.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and substantiate that a face-to-face encounter has occurred.

5. Section 410.40 is amended by--

A. In paragraph (c)(3)(ii), the word “fro” is revised to read “from.”

B. Redesignating paragraph (d)(2) as (d)(2)(i).

C. Adding paragraph (d)(2)(ii).

The addition reads as follows:

**§410.40 Coverage of ambulance services.**

* * * * *

(d) * * *

(2) * * *

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed physician certification statement does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * * *

6. Section 410.59 is amended by adding paragraph (a)(4) to read as follows:

**§410.59 Outpatient occupational therapy services: Conditions.**

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

7. Section 410.60 is amended by adding paragraph (a)(4) to read as follows:

**§ 410.60 Outpatient physical therapy services: Conditions.**

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient functional limitations.

* * * * *

8. Section 410.61 is amended by revising paragraph (c) to read as follows:

**§410.61 Plan of treatment requirements for outpatient rehabilitation services.**

* * * * *

(c) Content of the plan. The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals that are consistent with the patient function reporting on claims for services.

* * * * *

9. Section 410.62 is amended by adding paragraph (a)(4) to read as follows:

**§ 410.62 Outpatient speech-language-pathology services: Conditions and exclusions.**

(a) * * *

(4) Claims submitted for furnished services contain prescribed information on patient

functional limitations.

* * * * *

10. Section 410.63 is amended by adding paragraph (a)(1)(viii) to read as follows:

**§410.63 Hepatitis B vaccine and blood clotting factors: Conditions.**

* * *

(a) * * *

(1) * * *

(viii) Persons diagnosed with diabetes mellitus.

* * * * *

11. Section 410.69 is amended by adding the definition "Anesthesia and related care" to paragraph (b) in alphabetical order to read as follows:

**§410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.**

* * * * *

(b) * * *

<u>Anesthesia and related care</u> includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished.

* * * * *

12. Section 410.78 is amending by revising the introductory text of paragraph (b) 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) 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, and behavioral counseling for obesity furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

13. Section 410.105 is amended by--

A. Revising paragraph (c)(1)(ii).

B. Adding new paragraph (d).

The revision and addition read as follows:

**§410.105 Requirement for coverage of CORF services.**

* * * * *

(c) * * *

(1) * * *

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals that are consistent with the patient function reporting on the claims for services.

* * * * *

(d) Claims submitted for physical therapy, occupational therapy or speech-language-pathology services, contain prescribed information on patient functional limitations.

14. Section 410.160 is amended by--

A. Redesignating paragraphs (b)(8) through (b)(13) as paragraphs (b)(9) through (b)(14).

B. Adding new paragraph (b)(8).

The addition reads as follows:

**§410.160 Part B annual deductible.**

* * * * *

(b) * * *

(8) Beginning January 1, 2011, a surgical service furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal screening test. A surgical service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal screening test means —a surgical service furnished on the same date as a planned colorectal cancer screening test as described in §410.37 of this part.

* * * * *

**PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES**

15. 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)).

16. 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, and behavioral counseling for obesity 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.

* * * * *

17. Section 414.90 is amended by--

A. In paragraph (b), revising the definitions "Group practice" and "Qualified registry."

B. Removing the term "Qualified electronic health record product".

C. Adding the definitions "Administrative claims," "Direct electronic health record (EHR) product," "Electronic health record (EHR) data submission vendor product," and "Group practice reporting option (GPRO) web-interface" in alphabetical order.

D. Revising paragraphs (c) and (d).

E. Redesignating paragraphs (e), (f), (g), (h), (i), and (j) as paragraphs (f), (g), (i), (j), (k), and (l), respectively.

F. Adding new paragraphs (e) and (h).

G. Revising newly designated paragraphs (f), (g), and (k).

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 the proposed PQRS quality measures. Under this reporting mechanism, CMS determines which measures an eligible professional or group practice reports.

Direct electronic health record (EHR) product means an electronic health record vendor's product and version that submits data on Physician Quality Reporting System measures directly to CMS.

Electronic health record (EHR) data submission vendor product means an electronic health record vendor's product or version that acts as an intermediary to submit data on Physician Quality Reporting System measures on behalf of an eligible professional or group practice.

* * * * *

Group practice means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

Group practice reporting option (GPRO) web-interface means a web product developed by CMS that is used by group practices that are selected to participate in the group practice reporting option (GPRO) to submit data on Physician Quality Reporting System quality measures.

* * * * *

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the Physician Quality Reporting System

qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide Physician Quality Reporting System data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year, CMS reserves the right to disqualify a registry for reporting periods occurring in the following year.

* * * * *

(c) Incentive payments. For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if --

(1) There are any quality measures that have been established under the Physician Quality Reporting System that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and

(2) If the eligible professional (or in the case of a group practice under paragraph (j) of this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i of this section for the group practice) to the Secretary data on such quality measures in accordance with the Physician Quality Reporting System for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the

applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

(3) The applicable quality percent is as follows:

(i) For 2007 and 2008, 1.5 percent.

(ii) For 2009 and 2010, 2.0 percent.

(iii) For 2011, 1.0 percent.

(iv) For 2012, 2013, and 2014, 0.5 percent.

(4) For purposes of this paragraph--

(i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the Physician Quality Reporting System to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the Physician Quality Reporting System group practice

reporting option, the eligible professional cannot individually qualify for a Physician Quality Reporting System incentive payment by meeting the requirements specified in paragraph (g) of this section.

(iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(d) Additional incentive payment. Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(i) and (ii) of this section, must be increased by 0.5 percentage points.

(1) In order to qualify for the additional incentive payment described in paragraph (d)(1) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures for purposes of this section for the applicable incentive year.

(ii) Have such data submitted on their behalf through a Maintenance of Certification program (as defined in paragraph (b) of this section) that meets:

(A) The criteria for a registry (as specified by CMS); or

(B) An alternative form and manner determined appropriate by the Secretary.

(iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program (as defined in paragraph (b) of this section) for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment (as defined in paragraph (b) of this section) for such year.

(2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information—

(i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(2)(ii) of this section, which may be in the form of a structural measure.

(ii) If requested by the Secretary, on the survey of patient experience with care.

(iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) Payment Adjustments. For 2015 and subsequent years, with respect to covered professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection.

(1) The applicable percent is as follows:

(i) For 2015, 98.5 percent; and

(ii) For 2016 and each subsequent year, 98 percent.

(2) [Reserved]

(f) Use of consensus-based quality measures. For measures selected for inclusion in the Physician Quality Reporting System quality measure set, CMS will use consensus-based quality

measures that meet one of the following criteria:

(1) 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.

(2) 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 entity with a contract under section 1890(a) of the Act, the Secretary may 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.

(3) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of quality measures applicable to services they furnish.

(g) *Requirements for the incentive payments.* In order to qualify to earn a Physician Quality Reporting System incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, (or in the case of a group practice under paragraph (i) of this section, by the group practice) must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (g)(1) of this section and using one of the reporting mechanisms specified in paragraph (g)(2) of this section.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual Physician Quality Reporting System quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of Physician Quality Reporting System measures groups by eligible professionals.

(2) *Reporting mechanisms.* For program year 2011 and subsequent program years, an eligible professional who wishes to participate in the Physician Quality Reporting System must report information on the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups identified by CMS in one of the following manners:

(i) Claims. Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual Physician Quality Reporting System measures or measures groups.

(B) [Reserved]

(ii) Registry. Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit

information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) Direct EHR product. Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) EHR data submission vendor. Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) Web-interface. For a group practices defined in paragraph (b) of this section, reporting individual Physician Quality Reporting System quality measures to CMS using a CMS web-interface in the form and manner and by the deadline specified by CMS.

(3) Although an eligible professional may attempt to qualify for the Physician Quality Reporting System incentive payment by reporting on both individual Physician Quality Reporting System quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one Physician Quality Reporting System incentive payment per TIN/NPI combination for a program year.

(h) Requirements for the payment adjustments. In order to satisfy the requirements for the Physician Quality Reporting System payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination (or in the case of

a group practice under paragraph (i) of this section, by the group practice) must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual Physician Quality Reporting System measures or Physician Quality Reporting System measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section and using one of the reporting mechanisms specified in paragraph (h)(2) of this section.

(1) 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 two years prior to the year in which the payment adjustment is applied.

(i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1—December 31 that fall two years prior to the year in which the payment adjustment is applied, is also available.

(ii) [Reserved]

(2) An eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) who wishes to participate in the Physician Quality Reporting System must report information on the individual Physician Quality Reporting System measures or Physician Quality Reporting System measures groups identified by CMS using one of the following reporting mechanisms:

(i) Claims. Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) Medicare Part B claims may not be reprocessed or reopened for the sole purpose or reporting on individual Physician Quality Reporting System measures or measures groups.

(B) [Reserved]

(ii) Qualified registry. Reporting the individual Physician Quality Reporting System quality measures or Physician Quality Reporting System measures groups to a qualified registry (as specified in paragraph (b) of this section) in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) Direct EHR product. Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) EHR data submission vendor. Reporting the individual Physician Quality Reporting System quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product (as defined in paragraph (b) of this section) by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) GPRO web-interface. For a group practices defined in paragraph (b) of this section that are comprised of 25 or more eligible professionals, reporting individual Physician Quality Reporting System quality measures to CMS using a CMS web-interface in the form and manner and by the deadline specified by CMS.

(vi) Administrative claims. For the 2015 and 2016 payment adjustments, reporting certain administrative claims individual Physician Quality Reporting System quality measures during the applicable reporting period. Eligible professionals and (or in the case of a group

practice under paragraph (i) of this section) that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Register to participate in the Physician Quality Reporting System using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional or group practice has performed services applicable to certain individual Physician Quality Reporting System quality measures.

(3) Although an eligible professional or group practice may attempt to meet the criteria for satisfactory reporting for the Physician Quality Reporting System payment adjustment by reporting on individual Physician Quality Reporting System quality measures or measures groups using more than one reporting mechanism (as specified in paragraph (h)(2) of this section), the eligible professional or group practice must satisfy the criteria for satisfactory reporting for the Physician Quality Reporting System payment adjustment under one reporting mechanism per TIN/NPI combination for a program year.

(i) Requirements for group practices. Under the Physician Quality Reporting System, a group practice (as defined in paragraph (b) of this section) must meet all of the following requirements:

(1) Meet the participation requirements specified by CMS for the Physician Quality Reporting System group practice reporting option.

(2) Be selected by CMS to participate in the Physician Quality Reporting System group practice reporting option.

(3) Report measures in the form and manner specified by CMS.

(4) Meet other requirements for satisfactory reporting specified by CMS.

(5) Meet participation requirements.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the Physician Quality Reporting System group practice reporting option for a program year, then for that program year the eligible professional must participate in the Physician Quality Reporting System via the group practice reporting option.

(ii) If, for the program year, the eligible professional participates in the Physician Quality Reporting System as part of a group practice (as identified by the TIN) that is not selected to participate in the Physician Quality Reporting System group practice reporting option for that program year, then the eligible professional may individually participate and qualify for a Physician Quality Reporting System incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

18. Section 414.92 is amended by --

A. Revising paragraphs (c)(2)(ii)(A)(5) and (c)(2)(ii)(A)(6).

B. Adding paragraph (f)(2)(i)(A) and reserving paragraph (f)(2)(i)(B).

C. Redesignating paragraph (g) as paragraph (h), and adding new paragraph (g).

The revision and addition reads as follows:

**§ 414.92 Electronic Prescribing Incentive Program.**

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(A) * * *

(5) Eligible professionals who achieve meaningful use during the respective 6 or 12-month payment adjustment reporting period.

(6) Eligible professionals who have registered to participate in the EHR Incentive Program and adopted Certified EHR Technology prior to application of the respective payment adjustment.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on the electronic prescribing measure.

(B) [Reserved]

Informal review. Eligible professionals (or in the case of reporting under paragraph (e) of this section, group practices) may seek an informal review of the determination that an eligible professional (or in the case of reporting under paragraph (e) of this section, group practices) did not meet the requirements for the 2013 incentive or the 2013 and 2014 payment adjustments.

(1) To request an informal review for the 2013 incentive, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(2) To request an informal review for the 2013 and 2014 payment adjustments, an eligible professional or group practices must submit a request to CMS by January 31 of the year in which the eligible professional is receiving the applicable payment adjustment. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

(3) CMS will provide a written response of CMS' determination within 90 days of the receipt of the request.

(i) All decisions based on the informal review are final.

(ii) There is no further review or appeal.

* * * * *

19. Section 414.610 is amended by revising paragraphs (c)(1)(ii), (c)(5)(ii), and (h) to read as follows:

**§414.610 Basis of payment.**

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2012, 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; and

(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, 2012, 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.

* * * * *

(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 December 31, 2012.

20. Section 414.904 is amended by revising paragraphs (d)(3)(ii), (d)(3)(iii) and (d)(3)(iv).

B. The revisions read as follows:

**§414.904 Average sales price as the basis for payment.**

* * * * *

(d) * * *

(3) * * *

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not a critical or medically necessary drug identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when--

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

* * * * *

21. Subpart N is added to Part 414 to read as follows:

**Subpart N--Value-Based Payment Modifier under the Physician Fee Schedule**

Sec.

414.1200 Basis and scope.

414.1205 Definitions.

414.1210 Application of the value-based payment modifier.

414.1215 Performance and payment adjustment periods for the value-based payment modifier.

414.1220 **Reporting mechanisms for the value-based payment modifier under the physician fee schedule.**

**414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.**

414.1230 Additional measures for groups of physicians.

414.1235 Cost measures.

414.1240 Attribution for quality of care and cost measures.

414.1245 Scoring methods for the value-based payment modifier.

414.1250 Benchmarks for quality of care measures.

414.1255 Benchmarks for cost measures.

414.1260 Composite scores.

414.1265 Reliability of measures.

414.1270 Payment adjustments.

414.1275 Payment modifier scoring methodology.

414.1280 Limitation of review.

414.1285 Inquiry process.

**Subpart N--Value-Based Payment Modifier under the Physician Fee Schedule**

**§ 414.1200 Basis and scope.**

(a) Basis. This part/section implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians under the Medicare physician fee schedule based on the quality of care furnished compared to cost during a performance period.

(b) Scope. This subpart sets forth the following:

(1) The application of the value-based payment modifier.

(2) Performance and payment adjustment periods.

(3) Reporting mechanisms for the value-based payment modifier.

(4) Alignment of PQRS quality of care measures with the quality composite of the value-based payment modifier.

(5) Additional measures for groups of physicians.

(6) Cost measures.

(7) Attribution for quality of care and cost measures.

(8) Scoring methods for the value-based payment modifier.

(9) Benchmarks for quality of care measures.

(10) Benchmarks for cost measures.

(11) Composite scores.

(12) Reliability of measures.

(13) Payment adjustments.

(14) Payment modifier scoring methodology.

(15) Limitation of review.

(16) Inquiry process.

**§ 414.1205 Definitions.**

As used in this section, unless otherwise indicated—

Accountable care organization (ACO) has the same meaning given this term under §425.20 of this chapter.

Critical access hospital has the same meaning given this term under §400.202 of this chapter.

Electronic health record (EHR) has the same meaning given this term under §414.92 of this chapter.

Eligible professional has the same meaning given this term under section1848(k)(5)(B) of the Act.

Federally Qualified Health Center has the same meaning given this term under §405.2401(b) of this chapter.

Group of physicians means 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 Medicare billing rights to the TIN, as determined at the time the group of physicians is selected to participate under the Physician Quality Reporting System GPRO.

Performance rate mean the calculated rate for each quality or cost measure such as the percent of times that a particular clinical quality action was reported as being performed, or a particular outcome was attained, for the applicable persons to whom a measure applies as described in the denominator for the measure.

Physician has the same meaning given this term under section 1861(r) of the Act.

Physician Fee Schedule has the same meaning given this term under part 410 of this chapter.

Physician Quality Reporting System means the system established under section 1848(k) of the Act.

Risk score means the beneficiary risk score derived from the CMS Hierarchical Condition Categories (HCC) model.

Taxpayer Identification Number (TIN) has the same meaning given this term under §425.20 of this chapter.

Value-based payment modifier means the percentage by which amounts paid to a physician or group of physicians under the physician fee schedule are adjusted.

Value-based payment modifier satisfactory reporting criteria means the criteria for satisfactory reporting of data on Physician Quality Reporting System quality measures for the 2013 and 2014 incentive or the criteria for satisfactory reporting using the Physician Quality Reporting System administrative claims-based reporting mechanism, which is applicable to the 2015 and 2016 PQRS payment adjustment.

**§ 414.1210 Application of the value-based payment modifier.**

(a) The value-based payment modifier is applicable to the items and services furnished

under the Medicare Part B physician fee schedule by physicians in groups of physicians with 25 or more eligible professionals starting on January 1, 2015.

(b) Exceptions:

(1) Groups of physicians with 25 or more eligible professionals that are participating in the Medicare Shared Savings Program or the Pioneer ACO program.

(2) [Reserved]

**§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.**

(a) The performance period is calendar year 2013 for payment adjustments to be made in the calendar year 2015 payment adjustment period.

(b) The performance period is calendar year 2014 for payment adjustments to be made in the calendar year 2016 payment adjustment period.

**§ 414.1220 Reporting mechanisms for the value-based payment modifier under the physician fee schedule.**

Groups of physicians may submit data on quality of care measures as specified under the Physician Quality Reporting System and in § 414.90(g).

**§ 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 are eligible to report under the Physician Quality Reporting System starting in 2013 are used to calculate the value-based payment modifier program to the extent the group of physicians submits data on such measures.

**§ 414.1230 Additional measures for groups of physicians.**

The value-based payment modifier includes the following additional quality measures for all groups of physicians:

(a) A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes. The rate of potentially preventable hospital admissions for diabetes is a composite measure of uncontrolled diabetes, short term diabetes complications, long term diabetes complications and lower extremity amputation for diabetes.

(b) A composite rates of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia.

(c) Rates of an all-cause hospital readmissions measure.

(d) A 30-day post-discharge visit measure.

**§ 414.1235 Cost measures.**

Costs for groups of physicians are assessed based on the following five cost measures:

(a) Total per capita costs for all attributed beneficiaries; and

(b) Total per capita costs for all attributed beneficiaries with diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure.

(c) Total per capita costs include all payments made under Medicare Part A and Part B.

(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 each cost measure; that is--

(i) Total per capita costs; and

(ii) Total per capita costs for beneficiaries with the following conditions: coronary artery disease, COPD, diabetes, and heart failure.

**§ 414.1240 Attribution for quality of care and cost measures.**

Beneficiaries are attributed to groups of physicians using the method specified under the Physician Quality Reporting System.

**§ 414.1245 Scoring methods for the value-based payment modifier.**

For each quality of care and cost measure, a standardized score is calculated for each group of physicians by dividing--

(1) The difference between their performance rate and the benchmark, by

(2) The measure's standard deviation.

**§ 414.1250 Benchmarks for quality of care measures.**

The benchmark for each quality of care measure is the national mean for that measure's performance rate during the performance period. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of cases used to calculate the group of physician's performance rate.

**§ 414.1255 Benchmarks for cost measures.**

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. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of cases used to calculate the group of physician's performance rate.

**§ 414.1260 Composite scores.**

(a)(1) The standardized score for each quality of care measure is classified into one of the following equally weighted domains to determine the quality composite:

(i) Patient safety.

(ii) Patient experience.

(iii) Care coordination.

(iv) Clinical care.

(v) Population/community health.

(vi) Efficiency.

(2) If a domain includes no measure or does not reach the minimum case size in § 414.1265, the remaining domains are equally weighted to form the quality of care composite.

(b)(1) The standardized score for each cost measure is grouped into two separate and equally weighted domains to determine the cost composite:

(i) Total per capita costs for all attributed beneficiaries (one measures); and

(ii) Total per capita costs for all attributed beneficiaries with specific conditions: diabetes, coronary artery disease, chronic obstructive pulmonary disease, or heart failure (four measures).

(2) Measures within each domain are equally weighted.

**§ 414.1265 Reliability of measures.**

To calculate a composite score for a quality or cost measure based on claims, a group of physicians must have 20 or more cases for that measure.

(a) Where a group of physicians has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(b) Where a reliable quality of care composite or cost composite cannot be calculated, payments are not adjusted.

**§ 414.1270 Payment adjustments.**

(a) Downward payment adjustments. For a group of physicians with 25 or more eligible professionals that:

(1) Does not meet the value-based payment modifier satisfactory reporting criteria, payments for items and services under the physician fee schedule will be adjusted downward by 1.0 percent.

(2) Does meet the value-based payment modifier satisfactory reporting criteria, elects that their value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs), payments for items and services under the physician fee schedule are adjusted downward by up to 1.0 percent as specified in § 414.1275.

(b) Upward payment adjustments. If a group of physicians with 25 or more eligible professionals does meet the value-based payment modifier satisfactory reporting criteria and 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 subsection (a) above and applied as specified in § 414.1275.

**§ 414.1275** Payment modifier scoring methodology..

(a) The value-based payment modifier amount for a group of physicians that elects the quality-tiering approach is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

(b) Groups of physicians' quality composite and cost composite are classified into high, average, and low categories based on whether the composites are statistically above, not different from, or below the mean composite scores.

(c) The following value-based payment modifier amounts apply:

**Value-Based Payment Modifier Amounts for Groups of Physicians Requesting 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 reporting Physician Quality Reporting System quality measures through the GPRO using the web-interface, claims, registries, or EHRs, and average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

(d) Groups of physicians that have an attributed beneficiary population with an average

risk score in the top 25 percent of the risk scores of beneficiaries nationwide and that satisfactorily report data on quality measures through the Physician Quality Reporting System GPRO using the web-interface, claims, registries, or EHRs reporting mechanisms, receive a greater upward payment adjustment as follows:

(1) Groups of physicians classified as high quality/low cost receive an upward adjustment of +3x (rather than +2x) and

(2) Groups of physicians classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +2x (rather than +1x).

**§ 414.1280 Limitation of review.**

(a) There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of all of the following:

(1) The establishment of the value-based payment modifier.

(2) The evaluation of the quality of care composite, including the establishment of appropriate measure of the quality of care.

(3) The evaluation of costs composite, including establishment of appropriate measures of costs.

(4) The dates of implementation of the value-based payment modifier.

(5) The specification of the initial performance period and any other performance period.

(6) The application of the value-based payment modifier.

(7) The determination of costs.

**§ 414.1285** Inquiry process.

After the dissemination of the annual Physician Feedback reports, a group of physicians may contact CMS to inquire about its report and the calculation of the value-based payment modifier.

**PART 415--SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS,**

**SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS**

22. The authority citation for part 415 continues to read as follows:

**Authority**: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**§415.130 [Amended]**

23. In §415.130(d)(1) and (d)(2), remove the reference to "December 31, 2011" and add in its place the reference to "June 30, 2012."

**PART 421--MEDICARE CONTRACTING**

24. The authority citation for part 421 continues to read as follows:

**Authority**: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart F--[Removed and Reserved]**

25. Subpart F is removed and reserved.

**PART 423--VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**

26. 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).

27. Section 423.160 is amended by--

A. Revising paragraphs (a)(3)(iv), (b)(1)(ii), and (b)(2)(ii) introductory text

B. Adding paragraphs (b)(1)(iii), (b)(2)(iii), (b)(5)(i), and (b)(5)(ii).

The revisions and additions read as follows:

**§423.160 Standards for electronic prescribing.**

(a) * * *

(3) * * *

(iv) Until November 1, 2013, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. After January 1, 2012, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser must utilize the NCPCP SCRIPT

* * * * *

(b) * * *

(1) * * *

(ii) Before November 1, 2013 the standards specified in paragraphs (b)(2)(ii) and (b)(3) of this section.

(iii) On or after November 1, 2013, the standards specified in paragraphs (b)(2)(ii) and (b)(3) through (b)(6) of this section.

(2) * * *

(ii) The National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(v) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

* * * * *

(iii) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 10 release 6 approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or related prescription related information between prescribers and dispensers.

* * * * *

(5) * * *

(i)Formulary and benefits. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 3.0), January 2011(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. 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; or The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 3.0), January 2011(incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

* * * * *

28. Subpart F, consisting of §421.500 through §421.505 is removed and reserved.

**PART 425--MEDICARE SHARED SAVINGS PROGRAM**

29. 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).

30. 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 the GPRO 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.

31. Section 425.504 is amended by adding paragraph (b) to read as follows:

**§425.504 Incorporating reporting requirements related to the Physician Quality Reporting System.**

* * * * *

(b) Physician Quality Reporting System payment adjustment.

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under §425.500 using the GPRO web interface established by CMS, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(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.

(ii) Under the Shared Savings Program, an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under Subpart F of this part during the reporting period for a year, as defined in

paragraph (b)(6) of this section, according to the method of submission established by CMS under the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment.

(3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of a Physician Quality Reporting System payment adjustment, each ACO supplier/provider who is an eligible professional, will receive a payment adjustment, as described in paragraph (b)(5) of this section.

(4) ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot satisfactorily report for purposes of a Physician Quality Reporting System payment adjustment outside of the Medicare Shared Savings Program.

(5) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program, 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.

(i) The applicable percent for 2015 is 98.5 percent.

(ii) The applicable percent for 2016 and subsequent years is 98.0 percent.

(6) 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.

**PART 486--CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS**

32. The authority citation for part 486 continues to read as follows:

**Authority:** Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

33. Section 486.106 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

**§486.106 Condition for coverage: Referral for service and preservation of records.**

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a nonphysician practitioner as provided in §410.32(a) of this chapter or by a nonphysician practitioner as provided in §410.32(a)(2) and records are properly preserved.

(a) Standard—referral by a physician or nonphysician practitioners. Portable X-ray examinations are performed only on the order of a physician licensed to practice in the State or by a nonphysician practitioner acting within the scope of State law. Such nonphysician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph. The supplier's records show that:

(1) The portable X-ray test was ordered by a licensed physician or a nonphysician practitioner acting within the State scope of law; and

(2) Such physician or nonphysician practitioner's written, signed order specifies the reason a portable X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) Standard—records of examinations performed. The supplier makes for each patient a record of the date of the portable X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician or nonphysician practitioner, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

* * * * *

**PART 495--STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM**

34. The authority citation for part 495 continues to read as follows:

**Authority**: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

35. Section 495.8 is amended by revising paragraph (a)(2)(v) to read as follows:

**§ 495.8 Demonstration of meaningful use criteria.**

(a) * * *

(2) * * *

(v) Exception for Medicare EPs for PY 2012 and 2013—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot. To satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

* * * * *

**Authority:** (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: June 27, 2012

**Marilyn Tavenner,**

Acting Administrator,

Centers for Medicare &

Medicaid Services

Approved: June 28, 2012

**Kathleen Sebelius,**

Secretary.

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