DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, and 495

[CMS–1524–P]

RIN 0938–AQ25

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012

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

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also addresses, implements or discusses certain provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and the Medicare Improvements for Patients and Providers Act of 2008. In addition, this proposed rule discusses payments for Part B drugs; Physician Quality Reporting System; the Electronic Prescribing (eRx) Incentive Program; the Physician Resource-Use Feedback Program and the value modifier; productivity adjustment for ambulatory surgical center payment system and the ambulance, clinical laboratory, and durable medical equipment prosthetics orthotics and supplies (DMEPOS) fee schedules; and other Part B related issues. (See the Table of Contents for a listing of the specific issues addressed in this proposed rule.)

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 30, 2011.

ADDRESSES: In commenting, please refer to file code CMS–1524–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–1524–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–1524–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) 786–1066 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:

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

Elizabeth Truong, (410) 786–6005, or Sara Vitolo, (410) 786–5714, for issues related to potentially misvalued services.

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

Sara Vitolo, (410) 786–5714, for issues related to malpractice RVUs.

Michael Moore, (410) 786–6830, for issues related to geographic practice cost indices.

Elizabeth Truong, (410) 786–6005, for issues related to the sustainable growth rate, or the anesthesia or physician fee schedule conversion factors.

Bonny Dahm, (410) 786–4006, for issues related to payment for covered outpatient drugs and biologicals.

Claudia Lamm, (410) 786–3421, for issues related to the chiropractic services demonstration budget neutrality issue.

Jamie Hermansen, (410) 786–2064, or Stephanie Frilling, (410) 786–4507 for issues related to the annual wellness visit.

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system, incentives for Electronic Prescribing (eRx) and Physician Compare.

Gift Tee, (410) 786–9316, for issues related to the Physician Resource Use Feedback Program and physician value modifier.

Stephanie Frilling, (410) 786–4507 for issues related to the 3-day Payment Window.

Pam West, (410) 786–2302, for issues related to the technical corrections.

Rebecca Cole or Erin Smith, (410) 786–4497, for issues related to physician payment not previously identified.

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 regulations.gov Web site (*http://www.regulations.gov*) as soon as possible after they have been received: Follow the search instructions on that Web site to view public comments.

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

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Regulations Text

Acronyms

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

AA—Anesthesiologist assistant
AACE—American Association of Clinical Endocrinologists
AACVPR—American Association of Cardiovascular and Pulmonary Rehabilitation
AADE—American Association of Diabetes Educators
AANA—American Association of Nurse Anesthetists
ABMS—American Board of Medical Specialties
ABN—Advanced Beneficiary Notice
ACC—American College of Cardiology
ACGME—Accreditation Council on Graduate Medical Education
ACLS—Advanced cardiac life support
ACP—American College of Physicians
ACR—American College of Radiology
ACS—American Community Survey
ADL—Activities of daily living
AED—Automated external defibrillator
AFROC—Association of Freestanding Radiation Oncology Centers
AFS—Ambulance Fee Schedule
AHA—American Heart Association
AHFS–DI—American Hospital Formulary Service-Drug Information
AHRQ—[HHS] Agency for Healthcare Research and Quality
AMA—American Medical Association
AMA RUC—[AMA's Specialty Society] Relative (Value) Update Committee
AMA–DE—American Medical Association Drug Evaluations
AMI—Acute Myocardial Infarction
AMP—Average Manufacturer Price
AO—Accreditation organization
AOA—American Osteopathic Association
APA—American Psychological Association
APC—Administrative Procedures Act
APTA—American Physical Therapy Association
ARRA—American Recovery and Reinvestment Act (Pub. L. 111–5)
ASC—Ambulatory surgical center
ASP—Average Sales Price
ASPE—Assistant Secretary of Planning and Evaluation (ASPE)
ASRT—American Society of Radiologic Technologists
ASTRO—American Society for Therapeutic Radiology and Oncology
ATA—American Telemedicine Association
AWP—Average wholesale price
AWV—Annual Wellness Visit
BBA—Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA—[Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLS—Bureau of Labor and Statistics
BMD—Bone mineral density
BMI—Body mass index
BN—Budget neutrality
BPM—Benefit Policy Manual
CABG—Coronary artery bypass graft
CAD—Coronary artery disease
CAH—Critical Access Hospital
CAHEA—Committee on Allied Health Education and Accreditation
CAP—Competitive acquisition program
CARE—Continuity Assessment Record and Evaluation
CBIC—Competitive Bidding Implementation Contractor
CBP—Competitive Bidding Program
CBSA—Core-Based Statistical Area
CDC—Centers for Disease Control and Prevention
CEM—Cardiac Event Monitoring
CF—Conversion Factor
CFC—Conditions for Coverage
CFR—Code of Federal Regulations
CKD—Chronic kidney disease
CLFS—Clinical laboratory fee schedule
CMA—California Medical Association
CMD—Contractor Medical Director
CME—Continuing medical education
CMHC—Community Mental Health Center
CMPs—Civil money penalties
CMS—Centers for Medicare & Medicaid Services
CNS—Clinical Nurse Specialist
CoP—Condition of participation
COPD—Chronic obstructive pulmonary disease
CORF—Comprehensive Outpatient Rehabilitation Facility
COS—Cost of service
CPEP—Clinical Practice Expert Panel
CPI—Consumer Price Index
CPI–U Consumer price index for urban consumers
CPR—Cardiopulmonary resuscitation
CPT—[Physicians] Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)
CQM—Clinical quality measures
CR—Cardiac rehabilitation
CRF—Chronic Renal Failure
CRNA—Certified registered nurse anesthetist
CROs—Clinical research organizations
CRP—Canalith repositioning
CRT—Certified respiratory therapist
CSC—Computer Sciences Corporation
CSW—Clinical social worker
CT—Computed Tomography
CTA—Computed Tomography Angography
CWF—Common Working File
CY—Calendar Year
D.O.—Doctor of Osteopathy
DEA—Drug Enforcement Agency
DHHS—Department of Health and Human Services
DHS—Designated health services

DME—Durable Medical Equipment
DMEPOS—Durable medical equipment, prosthetics, orthotics, and supplies
DOJ—Department of Justice
DOQ—Doctors Office Quality
DOS—Date of service
DOTPA—Development of Outpatient Therapy Alternatives
DRA—Deficit Reduction Act of 2005 (Pub. L. 109–171)
DSMT—Diabetes Self-Management Training Services
DXA CPT—Dual energy X-ray absorptiometry
E/M—Evaluation and Management Medicare Services
ECG—Electrocardiogram
EDI—Electronic data interchange
EEG—Electroencephalogram
EGC—Electrocardiogram
EHR—Electronic health record
EKG—Electrocardiogram
EMG—Electromyogram
EMTALA—Emergency Medical Treatment and Active Labor Act
EOG—Electro-oculogram
EPO—Erythopoeitin
EPs—Eligible Professional
eRx—Electronic Prescribing
ESO—Endoscopy Supplies
ESRD—End-Stage Renal Disease
FAA—Federal Aviation Administration
FAX—Facsimile
FDA—Food and Drug Administration (HHS)
FFS—Fee-for-service
FISH—In Situ Hybridization Testing
FOTO—Focus On Therapeutic Outcomes
FQHC—Federally Qualified Health Center
FQHC—Federally Qualified Health Center
FR—**Federal Register**
FTE—full time equivalent
GAF—Geographic adjustment factor
GAFs—Geographic Adjustment Factors
GAO—Government Accountability Office
GEM—Generating Medicare [Physician Quality Performance Measurement Results]
GFR—Glomerular filtration rate
GME—Graduate Medical Education
GPCIs—Geographic Practice Cost Indices
GPO—Group purchasing organization
GPOs—Group purchasing organizations
GPRO—Group Practice Reporting Option
GPS—Geographic Positioning System
GQ—Via asynchronous telecommunications system
GSA—General Services Administration
GT—Growth Target
HAC—Hospital-acquired conditions
HBAI—Health and Behavior Assessment and Intervention
HCC—Hierarchal Condition Category
HCPAC—Health Care Professionals Advisory Committee
HCPCS—Healthcare Common Procedure Coding System
HCRIS—Healthcare Cost Report Information System
HDL/LDL—High-density lipoprotein/Low-density lipoprotein
HDRT—High dose radiation therapy
HEMS—Helicopter Emergency Medical Services
HH PPS—Home Health Prospective Payment System
HHA—Home health agency
HHRG—Home health resource group
HHS—[Department of] Health and Human Services
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)
HITSP—Healthcare Information Technology Standards Panel
HIV—Human immunodeficiency virus
HMO—Health Maintenance Organization
HOPD—Hospital outpatient department
HPSA—Health Professional Shortage Area
HRA—Health Risk Assessment
HRSA—Health Resources Services Administration (HHS)
HSIP—HPSA Surgical Incentive Program
HUD—Department of Housing and Urban Development
HUD—Housing and Urban Development
IACS—Individuals Access to CMS Systems
IADL—Instrumental activities of daily living
ICD—International Classification of Diseases
ICF—Intermediate care facilities
ICF—International Classification of Functioning, Disability and Health
ICR—Intensive cardiac rehabilitation
ICR—Information collection requirement
IDE—Investigational device exemption
IDTF—Independent diagnostic testing facility
IFC—Interim final rule with comment period
IGI—IHS Global Insight, Inc.
IME—Indirect Medical Education
IMRT—Intensity-Modulated Radiation Therapy
INR—International Normalized Ratio
IOM—Institute of Medicine
IOM—Internet Only Manual
IPCI—indirect practice cost index
IPPE—Initial preventive physical examination
IPPS—Inpatient prospective payment system
IRS—Internal Revenue Service
ISO—Insurance services office
IVD—Ischemic Vascular Disease
IVIG—Intravenous immune globulin
IWPUT—Intra-service work per unit of time
JRCERT—Joint Review Committee on Education in Radiologic Technology
KDE—Kidney Disease Education
LCD—Local coverage determination
LOPS—loss of protective sensation
LUGPA—Large Urology Group Practice Association
M.D.—Doctor of Medicine
MA—Medicare Advantage program
MAC—Medicare Administrative Contractor
MA–PD—Medicare Advantage-Prescription Drug Plans
MAV—Measure Applicability Validation
MCMP—Medicare Care Management Performance
MCP—Monthly Capitation Payment
MDRD—Modification of Diet in Renal Disease
MedCAC—Medicare Evidence Development and Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee (MCAC))
MedPAC—Medicare Payment Advisory Commission
MEI—Medicare Economic Index
MGMA—Medical Group Management Association
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)
MNT—Medical Nutrition Therapy
MOC—Maintenance of certification
MP—Malpractice
MPC—Multispecialty Points of Comparison
MPPR—Multiple Procedure Payment Reduction Policy
MQSA—Mammography Quality Standards Act of 1992 (Pub. L. 102–539)
MRA—Magnetic Resonance Angiography
MRI—Magnetic Resonance Imaging
MSA—Metropolitan Statistical Area
MSP—Medicare Secondary Payer
MUE—Medically Unlikely Edit
NAICS—North American Industry Classification System
NBRC—National Board for Respiratory Care
NCCI—National Correct Coding Initiative
NCD—National Coverage Determination
NCQA—National Committee for Quality Assurance
NCQDIS—National Coalition of Quality Diagnostic Imaging Services
NDC—National Drug Codes
NF—Nursing facility
NISTA—National Institute of Standards and Technology Act
NP—Nurse practitioner
NPI—National Provider Identifier
NPP—Nonphysician practitioner
NPPES—National Plan & Provider Enumeration System
NPPs—Nonphysician Practioners
NQF—National Quality Forum
NRC—Nuclear Regulatory Commission
NSQIP—National Surgical Quality Improvement Program
NTSB—National Transportation Safety Board
NUBC—National Uniform Billing Committee
OACT—[CMS] Office of the Actuary
OBRA—Omnibus Budget Reconciliation Act
OCR—Optical Character Recognition
ODF—Open door forum
OES—Occupational Employment Statistics
OGPE—Oxygen generating portable equipment
OIG—Office of the Inspector General
OMB—Office of Management and Budget
ONC—[HHS] Office of the National Coordinator for Health IT
OPPS—Outpatient prospective payment system
OSCAR—Online Survey and Certification and Reporting
PA—Physician Assistant
PACE—Program of All-inclusive Care for the Elderly
PACMBPRA—Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (Pub. L. 111–192)
PAT—Performance assessment tool

PC—Professional Components
PCI—Percutaneous coronary intervention
PCIP—Primary Care Incentive Payment Program
PDP—Prescription drug plan
PE—Practice Expense
PE/HR—Practice expense per hour
PEAC—Practice Expense Advisory Committee
PECOS—Provider Enrollment Chain and Ownership System
PERC—Practice Expense Review Committee
PFS—Physician Fee Schedule
PGP—[Medicare] Physician Group Practice
PHI—Protected health information
PHP—Partial hospitalization program
PIM—[Medicare] Program Integrity Manual
PLI—Professional liability insurance
POA—Present on admission
POC—Plan of care
PODs—Physician owned distributors
PPATRA—Physician Payment and Therapy Relief Act
PPI—Producer price index
PPIS—Physician Practice Expense Information Survey
PPPS—Personalized Prevention Plan Services
PPS—Prospective payment system
PPTA—Plasma Protein Therapeutics Association
PQRI—Physician Quality Reporting Initiative
PR—Pulmonary rehabilitation
PRA—Paperwork Reduction Act
PSA—Physician scarcity areas
PT—Physical therapy
PTA—Physical therapy assistant
PTCA—Percutaneous transluminal coronary angioplasty
PVBP—Physician and Other Health Professional Value-Based Purchasing Workgroup
QDCs—(Physician Quality Reporting System) Quality Data Codes
RA—Radiology assistant
RAC—Medicare Recovery Audit Contractor
RBMA—Radiology Business Management Association
RFA—Regulatory Flexibility Act
RHC—Rural Health Clinic
RHQDAPU—Reporting Hospital Quality Data Annual Payment Update Program
RIA—Regulatory impact analysis
RN—Registered nurse
RNAC—Reasonable net acquisition cost
RPA—Radiology practitioner assistant
RRT—Registered respiratory therapist
RUC—[AMA's Specialty Society] Relative (Value) Update Committee
RVRBS—Resource-Based Relative Value Scale
RVU—Relative Value Unit
SBA—Small Business Administration
SCHIP—State Children's Health Insurance Programs
SDW—Special Disability Workload
SGR—Sustainable growth rate
SLP—Speech-language pathology
SMS—Socioeconomic Monitoring Surveys
SMS—Monitoring Survey
SMS—[AMAs] Socioeconomic Monitoring System
SNF—Skilled Nursing Facility
SOR—System of record
SRS—Stereotactic radiosurgery
SSA—Social Security Administration
SSI—Social Security Income
STARS—Services Tracking and Reporting System
STATS—Short Term Alternatives for Therapy Services
STS—Society for Thoracic Surgeons
TC—Technical Components
TIN—Tax identification number
TJC—Joint Commission
TRHCA—Tax Relief and Health Care Act of 2006 (Pub. L. 109–432)
TTO—Transtracheal oxygen
UAF—Update Adjustment Factor
UPMC—University of Pittsburgh Medical Center
URAC—Utilization Review Accreditation Committee
USDE—United States Department of Education
USP–DI—United States Pharmacopoeia-Drug Information
VA—Department of Veterans Affairs
VBP—Value-based purchasing
WAC—Wholesale Acquisition Cost
WAMP—Widely available market price
WAMP—Widely Available Market Price
WHO—World Health Organization

Addenda Available Only Through the Internet on the CMS Web Site

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, beginning with the CY 2012 PFS proposed rule, the PFS Addenda will 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 are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2012 PFS proposed rule, refer to item CMS–1524–P. For complete details on the availability of the Addenda referenced in this proposed rule, we refer readers to section VIII. of this proposed rule. Readers who experience any problems accessing any of the Addenda or other documents referenced in this proposed rule and posted on the CMS Web site identified above should contact Erin Smith at (410) 786–4497.

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 2010 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. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The Act requires that payments under the physician fee schedule (PFS) are based on 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, practice expense (PE), and malpractice 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 social workers) that are permitted to furnish and bill Medicare under the PFS for their services.

A. Development of the Relative Value System

1. 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 malpractice RVUs were based on average allowable charges.

The physician work RVUs established for the implementation of the fee schedule in January 1992 was 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 (DHHS). 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's (AMA's) Specialty Society Relative Value Update Committee (RUC).

2. 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 RVUs.

We established the resource-based PE RVUs for each physician's 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 physician's service in both the office setting and out-of-office setting. We have since refined and revised these inputs based on recommendations from the AMA RUC. The AMA's SMS data provided aggregate specialty-specific information on hours worked and PEs.

Separate PE RVUs are established for procedures that can be performed 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 providing the service, apart from payment under the PFS. The nonfacility RVUs reflect all of the direct and indirect PEs of providing 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 calendar year (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 and provided for a 4-year transition for the new PE RVUs under this new methodology. This transition ended in CY 2010 and direct PE RVUs are calculated in CY 2012 using this methodology, unless otherwise noted.

In the CY 2010 PFS final rule with comment period (74 FR 61749), we updated the PE/hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties. 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 2012, the third year of the transition, PE RVUs are calculated based on a 75/25 blend of the new PE RVUs developed using the PPIS data and the previous PE RVUs based on the SMS and supplemental survey data.

3. Resource-Based Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based malpractice RVUs for services furnished on or after CY 2000. The resource-based malpractice RVUs were implemented in the PFS final rule 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. In the CY 2010 PFS final rule with comment period (74 FR 61758), we implemented the Second Five-Year Review and update of the malpractice RVUs. In the CY 2011 PFS final rule with comment period, we described our approach for determining malpractice RVUs for new or revised codes that become effective before the next Five Year Review and update (75 FR 73208). Accordingly, to develop the CY 2012 malpractice RVUs for new or revised codes we cross-walked the new or revised code to the malpractice RVUs of a similar source code and adjusted for differences in work (or, if greater, the clinical labor portion of the fully implemented PE RVUs) between the source code and the new or revised code.

4. 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. 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 initiated in the CY 2010 PFS final rule with comment period where we solicited candidate codes from the public for this review (74 FR 61941). Proposed revisions to work RVUs and corresponding changes to PE and malpractice RVUs affecting payment for physicians' services for the Fourth Five-Year Review of Work RVUs were published in a separate notice (76 FR 32410). We will review public comments, make adjustments to our proposals in response to comments, as appropriate, and include final values in the CY 2012 PFS final rule with comment period, effective for services furnished beginning January 1, 2012.

In 1999, the AMA RUC established the Practice Expense Advisory Committee (PEAC) for the purpose of refining the direct PE inputs. Through March 2004, the PEAC provided recommendations to CMS for over 7,600 codes (all but a few hundred of the codes currently listed in the AMA's 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 thespecialty 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 2005 PFS final rule with comment period (69 FR 66236), we implemented the First Five-Year Review of the malpractice 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 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 practice expenses; (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 RBRVS (the so-called 'Harvard valued codes'); and (7) other codes determined to be appropriate by the Secretary.

5. Application of Budget Neutrality to Adjustments of RVUs

Budget neutrality 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 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.

B. Components of the Fee Schedule Payment Amounts

To calculate the payment for every physician's service, the components of the fee schedule (physician work, PE, and malpractice RVUs) are adjusted by a geographic practice cost index (GPCI). The GPCIs reflect the relative costs of physician work, PE, and malpractice 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:

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

C. Most Recent Changes to the Fee Schedule

The CY 2011 PFS final rule with comment period (75 FR 73170) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2010 interim RVUs and implemented interim RVUs for new and revised codes for CY 2011 to ensure that our payment systems are updated to reflect changes in medical practice and the relative values of services. The CY 2011 PFS final rule with comment period also addressed other policies, as well as certain provisions of the Affordable Care Act and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

In the CY 2011 PFS final rule with comment period, we announced the following for CY 2011: the total PFS update of −10.1 percent; the initial estimate for the sustainable growth rate of −13.4 percent; and the CF of $25.5217. These figures were calculated based on the statutory provisions in effect on November 2, 2010, when the CY 2011 PFS final rule was issued.

On December 30, 2010, we published a correction notice (76 FR 1670) to correct several technical and typographical errors that occurred in the CY 2011 PFS final rule with comment period. This correction notice announced a revised CF for CY 2011 of $25.4999.

On November 30, 2010, the Physician Payment and Therapy Relief Act of 2010 (PPATRA) (Pub. L. 111–286) was signed into law. Section 3 of Public Law 111–286 modified the policy finalized in the CY 2011 PFS final rule with comment period (75 FR 73241), effective January 1, 2011, regarding the payment reduction applied to multiple therapy services provided to the same patient on the same day in the office setting by one provider and paid for under the PFS (hereinafter, the therapy multiple procedure payment reduction (MPPR)). The PPATRA provision changed the therapy MPPR percentage from 25 to 20 percent of the PE component of payment for the second and subsequent ''always'' therapy services furnished in the office setting on the same day to the same patient by one provider, and excepted the payment reductions associated with the therapy MPPR from budget neutrality under the PFS.

On December 15, 2010, the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) was signed into law. Section 101 of Public Law 111–309 provided for a 1-year zero percent update for the CY 2011 PFS. As a result of the MMEA, the CY 2011 PFS

conversion factor was revised to $33.9764.

II. Provisions of the Proposed Rule for the Physician Fee Schedule

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 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 history 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 required to provide 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 practice expenses incurred per hour worked (PE/HR) 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 changed over to 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 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1848(c)(2)(H)(i) of the Act, which 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, sleep medicine, and spine surgery since these specialties are not separately recognized by Medicare, nor do we have a method to blend these data with Medicare-recognized specialty data.

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

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for 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 with respect to physician time.

For registered dietician services, the proposed 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 are four specialties whose utilization data will be newly incorporated into ratesetting for CY 2012. We are proposing to 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; and Intensive Cardiac Rehabilitation from Cardiology. Additionally, since section 1833(a)(1)(K) of the Act (as amended by section 3114 of the Affordable Care Act) requires that payment for services provided by a certified nurse midwife be paid at 100 percent of the PFS amount, this specialty will no longer be excluded from the ratesetting calculation. We are proposing to crosswalk the PE\HR data from Obstetrics/gynecology to Certified Nurse Midwife. These newly proposed changes are reflected in the ''PE HR'' file available on the CMS Web site under the supporting data files for the CY 2012 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 2012 is the third year of the 4 year transition to the PE RVUs calculated using the PPIS data. Therefore, in general, the CY 2012 PE RVUs are a 25 percent/75 percent blend of the previous PE RVUs based on the SMS and supplemental survey data and the new PE RVUS developed using the PPIS data as described previously.

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 required to provide 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 allocate 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 incorporate 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 perform the service to determine an initial indirect allocator. For example, if the direct portion of the PE RVUs for a given service were 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that performed the service, the initial indirect allocator would be 6.00 since 2.00 is 25 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 performing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties performing 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 performed independently or by different providers, or they may be performed 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 2, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirectpercentage (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 performed 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 primarily 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. We note that since specialty code 97 (physician assistant) is paid at a percentage of the PFS and therefore excluded from the ratesetting calculation, this specialty has been added to the table for CY 2012.

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.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
95	Competitive Acquisition Program (CAP) Vendor.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
1	Supplier of oxygen and/or oxygen related equipment.
2	Pedorthic personnel.
3	Medical supply company with pedorthic personnel.

• Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• Payment modifiers: Payment modifiers are accounted for in the creation of the file. 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.

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

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

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

Where:

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

usage = 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) and 0.5 for others.

price = price of the particular piece of equipment.

interest rate = 0.11.

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

maintenance = factor for maintenance; 0.05.

This interest rate was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). We solicit comment regarding reliable data on current prevailing loan rates for small businesses.

Note: The use of any particular conversion factor (CF) in Table 2 to illustrate the PE calculation has no effect on the resulting RVUs.

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TABLE 2: 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	DPEldb		13.32	77.52	5.74	5.74	0.00	6.12	6.12	0.00
(2) Supply cost (Sup)	Step 1	DPEldb		2.98	7.34	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp.)	Step 1	DPEldb		0.19	0.65	8.17	8.17	0.00	0.12	0.12	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.50	85.51	17.31	17.31	0.00	7.43	7.43	0.00
(5) Direct adjustment (Dir. Adj).	Steps 2-4	See footnote*		0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55
(6) Adjusted Labor	Steps 2-4	=Lab * Dir Adj	=(1)*(5)	7.26	42.27	3.13	3.13	0.00	3.34	3.34	0.00
(7) Adjusted Supplies	Steps 2-4	= Sup * Dir Adj	=(2)*(5)	1.63	4.00	1.85	1.85	0.00	0.65	0.65	0.00
(8) Adjusted Equipment	Steps 2-4	= Eqp * Dir Adj	=(3)*(5)	0.11	0.36	4.46	4.46	0.00	0.06	0.06	0.00
(9) Adjusted direct	Steps 2-4		=(6)+(7)+(8)	9.00	46.63	9.44	9.44	0.00	4.05	4.05	0.00
(10) Conversion Factor (CF)	Step 5	PFS		33.9764	33.9764	33.9764	33.9764	33.9764	33.9764	33.9764	33.9764
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.21	1.24	0.09	0.09	0.00	0.10	0.10	0.00
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.05	0.05	0.00	0.02	0.02	0.00
(13) Adj. equipment cost converted	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.13	0.13	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.26	1.37	0.28	0.28	0.00	0.12	0.12	0.00
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.26	0.18	0.29	0.29	0.29	0.29	0.29	0.29
(17) Ind_pct	Steps 6,7	Surveys		0.74	0.82	0.71	0.71	0.71	0.71	0.71	0.71
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8		((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)	((14)/(16)) * (17)
(19) Ind. Alloc. (1st part).	Step 8		See (18)	0.77	6.40	0.68	0.68	0.00	0.29	0.29	0.00
(20) Ind. Alloc. Formulas (2nd part).	Step 8	See Step 8		(15)	(15)	(15)	(11)	(15)	(15)	(11)	(15)
(21) Ind. Alloc. (2nd part).	Step 8		See (20)	0.97	33.75	0.31	0.09	0.22	0.27	0.10	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+(21)	1.74	40.15	0.99	0.77	0.22	0.56	0.39	0.17
(23) Indirect Adjustment (Ind. Adj.)	Steps 9-11	See footnote**		0.41	0.41	0.41	0.41	0.41	0.41	0.41	0.41
(24) Adjusted indirect allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.71	16.30	0.40	0.31	0.09	0.23	0.16	0.07
(25) Ind. Practice Cost Index (IPCI)	Steps 12-16	See Steps 12 - 16		1.12	0.82	0.90	0.90	0.90	0.93	0.93	0.93
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24) * (25)	0.79	13.32	0.36	0.28	0.08	0.21	0.15	0.06
(29) PE RVU	Step 18	=(Adj Dir + Adj Ind) * budn	=((14)+(26)) * budn	1.05	14.68	0.64	0.56	0.08	0.33	0.27	0.06

Note: PE RVUs in Table 2, row 29, may not match the values in 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]

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3. Changes to Direct PE Inputs

In this section, we discuss other specific CY 2012 proposals and changes related to direct PE inputs. The proposed changes that follow are included in the proposed CY 2012 direct PE database, which is available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/.*

a. Inverted Equipment Minutes

It has come to our attention that the minutes allocated for two particular equipment items have been inverted. This inversion affects three codes: 37232 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)), 37233 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)), and 37234 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)). In each case, the number of minutes allocated to the ''printer, dye sublimation (photo, color)'' (ED031) should be appropriately allocated to the ''stretcher'' (EF018). The number of minutes allocated to the stretcher should be appropriately allocated to the printer. Therefore, the proposed CY 2012 database includes direct PE input corrections to the times associated with the two equipment items in the three codes.

b. Labor and Supply Input Duplication

We recently identified a number of CPT codes with inadvertently duplicated labor and supply inputs in the PE database. We are proposing to remove the duplicate labor and supply inputs in the proposed CY 2012 database as detailed in Table 3.

TABLE 3—LABOR AND SUPPLY INPUT DUPLICATION

CPT Code	Short code descriptor	CMS Labor/ supply code	Description of labor/supply
12011	Repair superficial wound(s)	SA048	pack, minimum multi-specialty visit
15360	Apply cult derm sub t/a/l	SA054	pack, post-op incision care (suture)
19361	Breast reconstr w/lat flap	L037D	RN/LPN/MTA
21147	Reconstruct midface lefort	SA054	pack, post-op incision care (suture)
23515	Treat clavicle fracture	SA052	pack, post-op incision care (staple)
25415	Repair radius & ulna	SA052	pack, post-op incision care (staple)
	Repair radius & ulna	SA052	pack, post-op incision care (staple)
28005	Treat foot bone lesion	SA054	pack, post-op incision care (suture)
28456	Treat midfoot fracture	SA054	pack, post-op incision care (suture)
28485	Treat metatarsal fracture	SA054	pack, post-op incision care (suture)
32998	Perq rf ablate tx pul tumor	SG079	tape, surgical paper 1in (Micropore)
35501	Artery bypass graft	L037D	RN/LPN/MTA
	Artery bypass graft	SA048	pack, minimum multi-specialty visit
35509	Artery bypass graft	L037D	RN/LPN/MTA
	Artery bypass graft	SA048	pack, minimum multi-specialty visit
35601	Artery bypass graft	L037D	RN/LPN/MTA
	Artery bypass graft	SA048	pack, minimum multi-specialty visit
36147	Access av dial grft for eval	SB008	drape, sterile, c-arm, fluoro
	Access av dial grft for eval	SH026	Conray Inj (iothalamate 43%)
	Access av dial grft for eval	SK093	x-ray ID card (flashcard)
37231	Tib/per revasc stent & ather	SK034	film, x-ray 14in × 17in
45541	Correct rectal prolapse	SJ032	lubricating jelly (K–Y) (5gm uou)
45550	Repair rectum/remove sigmoid	SJ032	lubricating jelly (K–Y) (5gm uou)
46258	Remove in/ex hem grp w/fistu	SD003	anoscope
	Remove in/ex hem grp w/fistu	SD003	anoscope
	Remove in/ex hem grp w/fistu	SD003	anoscope
46261	Remove in/ex hem grps & fiss	SD003	anoscope
	Remove in/ex hem grps & fiss	SD003	anoscope
	Remove in/ex hem grps & fiss	SD003	anoscope
58563	Hysteroscopy ablation	SB027	gown, staff, impervious
64704	Revise hand/foot nerve	SA054	pack, post-op incision care (suture)
64726	Release foot/toe nerve	SA054	pack, post-op incision care (suture)
64782	Remove limb nerve lesion	SA054	pack, post-op incision care (suture)
65810	Drainage of eye	SA082	pack, ophthalmology visit (w-dilation)
67228	Treatment of retinal lesion	L038A	COMT/COT/RN/CST
	Treatment of retinal lesion	SA082	pack, ophthalmology visit (w-dilation)
	Treatment of retinal lesion	SH049	lidocaine 2% w-epi inj (Xylocaine w-epi)
76813	Ob us nuchal meas 1 gest	SK022	film, 8in × (ultrasound, MRI)
78730	Urinary bladder retention	SB044	underpad 2ft × 3ft (Chux)
88365	Insitu hybridization (fish)	SM016	eye shield, splash protection
91038	Esoph imped funct test > 1h	SJ016	denture cup
95875	Limb exercise test	SC051	syringe 10–12ml

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c. AMA RUC Recommendations for Moderation Sedation Direct PE Inputs

For services described by certain codes, the direct PE database includes nonfacility inputs that reflect the assumption that moderation sedation is inherent in the procedure. These codes are listed in Table 4. The AMA RUC has recently provided CMS with a recommendation that standardizes the nonfacility direct PE inputs that account for moderate sedation as typically furnished as part of these services. Specifically, the RUC recommended that the direct PE inputs allocated for moderate sedation include the following:

Clinical Labor Inputs: Registered Nurse (L051A) time that includes two minutes of time to initiate sedation, the number of minutes associated with the physician intra-service work time, and 15 minutes for every hour of patient recovery time for post-service patient monitoring.

Supply Inputs: ''Pack, conscious sedation'' (SA044) that includes: an angiocatheter 14g–24g, bandage, strip 0.75in × 3in, catheter, suction, dressing, 4in × 4.75in (Tegaderm), electrode, ECG (single), electrode, ground, gas, oxygen, gauze, sterile 4in × 4in, gloves, sterile, gown, surgical, sterile, iv infusion set, kit, iv starter, oxygen mask (1) and tubing (7 ft), pulse oximeter sensor probe wrap, stop cock, 3-way, swab-pad, alcohol, syringe 1ml, syringe-needle 3ml 22–26g, tape, surgical paper 1in (Micropore), tourniquet, and non-latex 1in × 18in.

Equipment Inputs: ''table, instrument, mobile'' (EF027), ''ECG, 3-channel (with SpO2, NIBP, temp, resp)'' (EQ011), ''IV infusion pump'' (EQ032), ''pulse oxymetry recording software (prolonged monitoring)'' (EQ212), and ''blood pressure monitor, ambulatory, w-battery charger'' (EQ269).

We have reviewed this recommendation and generally agree with these inputs. However, we note that the equipment item ''ECG, 3-channel (with SpO2, NIBP, temp, resp)'' (EQ011) incorporates the functionality of the equipment items ''pulse oxymetry recording software (prolonged monitoring)'' (EQ212), and ''blood pressure monitor, ambulatory, w-battery charger'' (EQ269). Therefore we have not included these two items as standard nonfacility inputs for moderation sedation.

We propose to accept the AMA RUC recommendation with the refinement as stated. The CY 2012 direct PE database reflects these proposed changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/.*

TABLE 4—INHERENT MODERATE SEDATION CODES VALUED IN THE NONFACILITY SETTING

CPT Code	Short descriptor
19298	Place breast rad tube/caths
20982	Ablate bone tumor(s) perq
22520	Percut vertebroplasty thor
22521	Percut vertebroplasty lumb
22526	Idet single level
22527	Idet 1 or more levels
31615	Visualization of windpipe
31620	Endobronchial us add-on
31622	Dx bronchoscope/wash
31623	Dx bronchoscope/brush
31624	Dx bronchoscope/lavage
31625	Bronchoscopy w/biopsy(s)
31626	Bronchoscopy w/markers
31627	Navigational bronchoscopy
31628	Bronchoscopy/lung bx each
31629	Bronchoscopy/needle bx each
31634	Bronch w/balloon occlusion
31635	Bronchoscopy w/fb removal
31645	Bronchoscopy clear airways
31646	Bronchoscopy reclear airway
31656	Bronchoscopy inj for x-ray
32201	Drain percut lung lesion
32550	Insert pleural cath
32553	Ins mark thor for rt perq
35471	Repair arterial blockage
35472	Repair arterial blockage
35475	Repair arterial blockage
35476	Repair venous blockage
36147	Access av dial grft for eval
36148	Access av dial grft for proc
36200	Place catheter in aorta
36245	Place catheter in artery
36481	Insertion of catheter vein
36555	Insert non-tunnel cv cath
36557	Insert tunneled cv cath
36558	Insert tunneled cv cath
36560	Insert tunneled cv cath
36561	Insert tunneled cv cath
36563	Insert tunneled cv cath
36565	Insert tunneled cv cath
36566	Insert tunneled cv cath
36568	Insert picc cath
36570	Insert picvad cath
36571	Insert picvad cath
36576	Repair tunneled cv cath
36578	Replace tunneled cv cath
36581	Replace tunneled cv cath
36582	Replace tunneled cv cath
36583	Replace tunneled cv cath
36585	Replace picvad cath
36590	Removal tunneled cv cath
36870	Percut thrombect av fistula
37183	Remove hepatic shunt (tips)
37184	Prim art mech thrombectomy
37185	Prim art m-thrombect add-on
37186	Sec art m-thrombect add-on
37187	Venous mech thrombectomy
37188	Venous m-thrombectomy add-on
37203	Transcatheter retrieval
37210	Embolization uterine fibroid
37220	Iliac revasc
37221	Iliac revasc w/stent
37222	Iliac revasc add-on
37223	Iliac revasc w/stent add-on
37224	Fem/popl revas w/tla

TABLE 4—INHERENT MODERATE SEDATION CODES VALUED IN THE NONFACILITY SETTING—Continued

CPT Code	Short descriptor
37225	Fem/popl revas w/ather
37226	Fem/popl revasc w/stent
37227	Fem/popl revasc stnt & ather
37228	Tib/per revasc w/tla
37229	Tib/per revasc w/ather
37230	Tib/per revasc w/stent
37231	Tib/per revasc stent & ather
37232	Tib/per revasc add-on
37233	Tibper revasc w/ather add-on
37234	Revsc opn/prq tib/pero stent
37235	Tib/per revasc stnt & ather
43200	Esophagus endoscopy
43201	Esoph scope w/submucous inj
43202	Esophagus endoscopy biopsy
43216	Esophagus endoscopy/lesion
43217	Esophagus endoscopy
43234	Upper gi endoscopy exam
43235	Uppr gi endoscopy diagnosis
43236	Uppr gi scope w/submuc inj
43239	Upper gi endoscopy biopsy
43453	Dilate esophagus
43456	Dilate esophagus
43458	Dilate esophagus
44385	Endoscopy of bowel pouch
44386	Endoscopy bowel pouch/biop
44388	Colonoscopy
44389	Colonoscopy with biopsy
44390	Colonoscopy for foreign body
44391	Colonoscopy for bleeding
44392	Colonoscopy & polypectomy
44393	Colonoscopy lesion removal
44394	Colonoscopy w/snare
44901	Drain app abscess percut
45303	Proctosigmoidoscopy dilate
45305	Proctosigmoidoscopy w/bx
45307	Proctosigmoidoscopy fb
45308	Proctosigmoidoscopy removal
45309	Proctosigmoidoscopy removal
45315	Proctosigmoidoscopy removal
45317	Proctosigmoidoscopy bleed
45320	Proctosigmoidoscopy ablate
45332	Sigmoidoscopy w/fb removal
45333	Sigmoidoscopy & polypectomy
45335	Sigmoidoscopy w/submuc inj
45338	Sigmoidoscopy w/tumr remove
45339	Sigmoidoscopy w/ablate tumr
45340	Sig w/balloon dilation
45378	Diagnostic colonoscopy
45379	Colonoscopy w/fb removal
45380	Colonoscopy and biopsy
45381	Colonoscopy submucous inj
45382	Colonoscopy/control bleeding
45383	Lesion removal colonoscopy
45384	Lesion remove colonoscopy
45385	Lesion removal colonoscopy
45386	Colonoscopy dilate stricture
47000	Needle biopsy of liver
47382	Percut ablate liver rf
47525	Change bile duct catheter
48511	Drain pancreatic pseudocyst
49021	Drain abdominal abscess
49041	Drain percut abdom abscess
49061	Drain percut retroper absc
49411	Ins mark abd/pel for rt perq
49418	Insert tun ip cath perc
49440	Place gastrostomy tube perc
49441	Place duod/jej tube perc
49442	Place cecostomy tube perc

TABLE 4—INHERENT MODERATE SEDATION CODES VALUED IN THE NON-FACILITY SETTING—Continued

CPT Code	Short descriptor
49446	Change g-tube to g-j perc
50021	Renal abscess percut drain
50200	Renal biopsy perq
50382	Change ureter stent percut
50384	Remove ureter stent percut
50385	Change stent via transureth
50386	Remove stent via transureth
50387	Change ext/int ureter stent
50592	Perc rf ablate renal tumor
50593	Perc cryo ablate renal tum
57155	Insert uteri tandems/ovoids
58823	Drain pelvic abscess percut
66720	Destruction ciliary body
69300	Revise external ear
77371	Srs multisource
77600	Hyperthermia treatment
77605	Hyperthermia treatment
77610	Hyperthermia treatment
77615	Hyperthermia treatment
92960	Cardioversion electric ext
93312	Echo transesophageal
93314	Echo transesophageal
93451	Right heart cath
93452	Left hrt cath w/ventrclgrphy
93453	R&I hrt cath w/ventriclgrphy
93454	Coronary artery angio s&i
93455	Coronary art/grft angio s&i
93456	Rhrt coronary artery angio
93457	Rhrt art/grft angio
93458	Lhrt artery/ventricle angio
93459	Lhrt art/grft angio
93460	R&I hrt art/ventricle angio
93461	R&I hrt art/ventricle angio
93464	Exercise w/hemodynamic meas
93505	Biopsy of heart lining
93566	Inject r ventr/atrial angio
93568	Inject pulm art hrt cath
93642	Electrophysiology evaluation

d. Updates to Price and Useful Life for Existing Direct Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking beginning with the CY 2012 PFS proposed rule.

During 2010, we received a request to update the price of ''tray, bone marrow biopsy-aspiration'' (SA062) from $24.27 to $34.47. The request included multiple invoices that documented updated prices for the supply item. We also received a request to update the useful life of ''holter monitor'' (EQ127) from 7 years to 5 years, based on its entry in the AHA's publication, ''Estimated Useful Lives of Depreciable Hospital Assets,'' which we use as a standard reference. In each of these cases, we are proposing to accept the updated inputs, as requested. The CY 2012 direct PE database reflects these proposed changes and is available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/.*

4. Development of Code-Specific PE RVUs

When creating G codes, we often develop work, PE, and malpractice RVUs by crosswalking the RVUs from similar (reference) codes. In most of these cases, the PE RVUs are directly crosswalked pending the availability of utilization data. Once that data is available, we crosswalk the direct PE inputs and develop PE RVUs using the regular practice expense methodology, including allocators that are derived from utilization data. For CY 2012, we are using this process to develop PE RVUs for the following services: 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); 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 (for example, 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); G0341 (Percutaneous islet cell transplant, includes portal vein catheterization and infusion); G0342 (Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion); G0343 (Laparotomy for islet cell transplant, includes portal vein catheterization and infusion); and G0365 (Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)). The values in Addendum B reflect the updated PE RVUs.

In addition, there is a series of G-codes describing surgical pathology services with PE RVUs historically valued outside of the regular PE methodology. These codes are: G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens); G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21–40 specimens); G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens); and G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens.) The PE RVUs for these codes were established as described in the CY 2009 PFS final rule with comment period (73 FR 69751). In reviewing these values for CY 2012, we noted that because the PE RVUs established through rulemaking in CY 2009 were neither developed using the regular PE methodology nor directly crosswalked from other codes, the PE RVUs for these codes were not adjusted to account for the CY 2011 MEI rebasing and revising, which is discussed in the CY 2011 PFS final rule with comment period (75 FR 73262). While it was technically appropriate to insulate the PE RVUs from that adjustment in CY 2011, upon further review, we believe adjusting these PE RVUs would result in more accurate payment rates relative to the RVUs for other PFS services. Therefore, we are proposing to adjust the PE RVUs for these codes by 1.182, the adjustment rate that accounted for the MEI rebasing and revising for CY 2011. The PE RVUs in Addendum B reflect the proposed updates.

5. Physician Time for Select Services

As we describe in section II.A.2.f. of this proposed rule with comment period, in creating the indirect practice cost index, 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.

During a review of the physician time data for the CY 2012 PFS rulemaking, we noted an anomaly regarding the physician time allotted to a series of group service codes that are listed in Table 5. We believe that the time associated with these codes reflects the typical amount of time spent by the practitioner in furnishing the group service. However, because the services are billed per patient receiving the service, the time for these codes should be divided by the typical number of patients per session. In reviewing the data used in the valuation of work RVUs for these services, we noted that in one vignette for these services, the typical group session consisted of 6 patients. Therefore we are proposing adjusted times for these services based on 6 patients. However, we seek comment on the typical number of patients seen per session for each of these services.

As a result of our review, we are also proposing to update our physician time file to reflect the physician time associated with certain G-codes that were previously missing from the file. Our proposed time values for these G-codes as well as the group service codes described previously can be found in the proposed CY 2012 Physician Time file, which is available on the CMS Web site under the supporting data files for the CY 2012 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/.*

TABLE 5—GROUP EDUCATION AND THERAPY CODES WITH PROPOSED TIME CHANGES

CPT Code	Short descriptor
90849	Multiple family group psytx
90853	Group psychotherapy
90857	Intac group psytx
92508	Speech/hearing therapy
96153	Intervene hlth/behave group
97150	Group therapeutic procedures
97804	Medical nutrition group
G0271	Group mnt 2 or more 30 mins
G0421	Ed svc ckd grp per session
G0109	Diab manage trn ind/group

B. Potentially Misvalued Services Under the Physician Fee Schedule

1. Valuing Services Under the PFS

As discussed in section I. of this proposed rule, in order 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.'' Additionally, the statute provides that the work component shall include activities that occur before and after direct patient contact. Furthermore, the statute specifies that with respect to surgical procedures, the valuation of the work component for the code must reflect a ''global'' concept in which pre-operative and post-operative physicians' services related to the procedure are also included.

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.A.2. and I.A.3. 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)(2)(C)(ii) of the Act specifies that the ''Secretary shall determine a number of practice expense relative value units for the services for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service.'' Furthermore, 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 and identify 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) of 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) of the Act which requires the Secretary to develop a validation process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same categorical criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.A.1. of this proposed rule, we generally establish physician work RVUs for new and revised codes based on our review of recommendations received from the AMA RUC. We also receive recommendations from the AMA RUC regarding direct PE inputs for services, which we evaluate in order to develop the PE RVUs under the PFS. The AMA RUC also provides recommendations to us on the values for codes that have been identified as potentially misvalued. To respond to concerns expressed by MedPAC, the Congress, and other stakeholders regarding accurate valuation of services under the PFS, the AMA RUC created the Five-Year Review Identification Workgroup in 2006. In addition to providing recommendations to us for work RVUs and physician times, the AMA RUC's Practice Expense Subcommittee reviews direct PE inputs (clinical labor, medical supplies, and medical equipment) for individual services.

In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC and MedPAC, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules. 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.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services under 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 physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to

decline as physicians become more familiar with the service and more efficient in furnishing it.'' That is, the amount of physician work needed to furnish an existing service may decrease when new technologies are incorporated. Services can also become overvalued when practice expenses decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently, reducing its cost per use. Likewise, services can become undervalued when physician work increases or practice expenses 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 the 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 or families of codes that have experienced substantial changes in practice expenses.
- Codes that are recently established for new technologies or services.
- Multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes which have not been subject to review since the implementation of the RBRVS (the so-called ''Harvard-valued codes'').
- 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 the RVUs 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 physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

Over the last several years, CMS, in conjunction with the AMA RUC, has 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, consistent with the new legislative requirements on this issue. In the current process, we request the AMA RUC to review potentially misvalued codes that we identify and make recommendations on revised work RVUs and/or direct PE inputs for those codes to us. The AMA RUC, through its own processes, also might identify and review potentially misvalued procedures. We then assess the recommended revised work RVUs and/or direct PE inputs and, in accordance with section 1848(c) of the Act, we determine if the recommendations constitute appropriate adjustments to the RVUs under the PFS.

Since CY 2009, as a part of the annual potentially misvalued code review, we have reviewed over 700 potentially misvalued codes to refine work RVUs and direct PE inputs in addition to continuing the comprehensive Five-Year Review process. 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 has included codes in all seven categories specified in section 1848(c)(2)(K)(ii) of the Act. That is, we have reviewed and assigned more appropriate values to—

- Codes and families of codes for which there has been the fastest growth;
- Codes or families of codes that have experienced substantial changes in practice expenses;
- Codes that were 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 had not been subject to review since the implementation of the RBRVS (''Harvard valued''); and
- Codes potentially misvalued as determined by the Secretary.

In this last category, we have previously proposed policies in CYs 2009, 2010, and 2011, and requested that the AMA RUC review codes for which there have been shifts in the site-of-service (that is, codes that were originally valued as being furnished in the inpatient setting, but that are now predominantly furnished on an outpatient basis), as well as codes that qualify as ''23-hour stay'' outpatient services (these services typically have lengthy hospital outpatient recovery periods). We note that a detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2011 PFS final rule with comment period (75 FR 73215 through 73216).

In CY 2011, we identified additional codes under section 1848(c)(2)(K)(ii) of the Act that we believe are ripe for review and referred them to the AMA RUC (75 FR 73215 through 73216). Specifically, we identified potentially misvalued codes in the category of ''Other codes determined to be appropriate by the Secretary,'' referring lists of codes with low work RVUs but that are high volume based on claims data as well as targeted key codes that the AMA RUC uses as reference services for valuing other services, termed ''multispecialty points of comparison'' services.

Since the publication of the CY 2011 PFS final rule with comment period, we released the Fourth Five-Year Review of Work (76 FR 32410), which discussed the identification and review of an additional 173 potentially misvalued codes. We initiated the Fourth Five-Year Review of work RVUs by soliciting public comments on potentially misvalued codes for all services included in the CY 2010 PFS final rule with comment period that was published in the **Federal Register** on November 25, 2009. In addition to the codes submitted by the commenters, we identified a number of potentially misvalued codes and requested the AMA RUC to review and provide recommendations. Our identification of potentially misvalued codes for the

Fourth Five-Year Review focused on two Affordable Care Act categories: Site-of-service anomaly codes and ''Harvard valued'' codes. As discussed in the Fourth Five-Year Review of Work (76 FR 32410), we sent the AMA RUC an initial list of 219 codes for review. Consistent with our past practice, we requested the AMA RUC to review codes on a ''family'' basis rather than in isolation in order to ensure that appropriate relativity in the system was retained. Consequently, the AMA RUC included additional codes for review, resulting in a total of 290 codes for the Fourth Five-Year Review of Work. Of those 290 codes, 53 were subsequently sent to the CPT Editorial Panel to consider coding changes, 14 were not reviewed by the AMA RUC (and subsequently not reviewed by us) because the specialty society that had originally requested the review in its public comments on the CY 2010 PFS final rule with comment period elected to withdraw the codes, 36 were not reviewed by the AMA RUC because their values were set as interim final in the CY 2011 PFS final rule with comment period, and 14 were not reviewed by us because they were noncovered services under Medicare. Therefore, the AMA RUC reviewed 173 of the 290 codes initially identified for the Fourth Five-Year Review of Work, and provided the recommendations that were addressed in detail in the Fourth Five-Year Review of Work (76 FR 32410). In addition, under the Fourth Five-Year Review of Work, we reviewed recommendations for five additional potentially misvalued codes from the Health Care Professionals Advisory Committee (HCPAC), a deliberative body of nonphysician practitioners that also convenes during the AMA RUC meeting. The HCPAC represents physician assistants, chiropractors, nurses, occupational therapists, optometrists, physical therapists, podiatrists, psychologists, audiologists, speech pathologists, social workers, and registered dieticians.

In summary, since CY 2009, CMS and the AMA RUC have addressed a number of potentially misvalued codes. For CY 2009, the AMA RUC recommended revised work values and/or PE inputs for 204 misvalued services (73 FR 69883). For CY 2010, an additional 113 codes were identified as misvalued and the AMA RUC provided us new recommendations for revised work RVUs and/or PE inputs for these codes to us as discussed in the CY 2010 PFS final rule with comment period (74 FR 61778). For CY 2011, CMS reviewed and adopted more appropriate values for 209 codes under the annual review of potentially misvalued codes. For CY 2012, we recently released the Fourth Five-Year Review of Work, which discussed the review of 173 potentially misvalued codes and proposed appropriate adjustments to RVUs. In section II.B.5.of this proposed rule, we also provide a list of codes identified for future consideration as part of the potentially misvalued codes initiative, that is, in addition to the codes that are part of the Fourth Five-Year Review of Work, as discussed in that section, we are requesting the AMA RUC review these codes and submit recommendations to us.

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 a new section 1848(c)(2)(L) of the Act, which specifies that the Secretary shall establish a formal process to validate RVUs value units 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 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), we solicited public comments on possible approaches and methodologies that we should consider for a validation process. We received a number of comments regarding possible approaches and methodologies for a validation process. As discussed in the CY 2011 PFS final rule with comment period (75 FR 73217), some commenters were skeptical that there could be viable alternative methods to the existing AMA RUC code review process for validating physician time and intensity that would preserve the appropriate relativity of specific physician's services under the current payment system. These commenters generally urged us to rely solely on the AMA RUC to provide valuations for services under the PFS.

While a number of commenters strongly opposed our plans to develop a formal validation process, many other commenters expressed support for the development and establishment of a system-wide validation process of the work RVUs under the PFS. As noted in the CY 2011 PFS final rule with comment period (75 FR 73217 through 73218), these commenters commended us for seeking new approaches to validation, as well as being open to suggestions from the public on this process. A number of commenters submitted technical advice and offered their time and expertise as resources for us to draw upon in any examination of possible approaches to developing a formal validation process.

However, in response to our solicitation of comments regarding time and motion studies, a number of commenters opposed the approach of using time and motion studies to validate estimates of physician time and intensity, stating that properly conducted time and motion studies are extraordinarily expensive and, given the thousands of codes paid under the PFS, it would be unlikely that all codes could be studied. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73218), we understand that these studies would require significant resources and we remain open to suggestions for other approaches to developing a formal validation process. We note that MedPAC suggested in its comment letter (75 FR 73218) that we should consider ''collecting data on a recurring basis from a cohort of practices and other facilities where physicians and nonphysician clinical practitioners work.'' As we stated previously, we intend to establish a more extensive validation process of RVUs in the future in accordance with the requirements of section 1848(c)(2)(L) of the Act.

While we received a modest number of comments specifically addressing technical and methodological aspects of developing a validation system, we believe it would be beneficial to provide an additional opportunity for stakeholders to submit comments on data sources and possible methodologies for developing a system-wide validation system. We are particularly interested in comments regarding data sources and studies which may be used to validate estimates of physician time and intensity that could be factored into the work RVUs, especially for services with rapid growth in Medicare expenditures, which is one of the Affordable Care Act

categories that the statute specifically directs us to examine. We are also soliciting comments regarding MedPAC's suggestion of ''collecting data on a recurring basis from a cohort of practices and other facilities where physicians and nonphysician clinical practitioners work.''

We plan to discuss the validation process in more detail in a future PFS rule once we have considered the matter further in conjunction with the public comments received on the CY 2011 rulemaking, as well as this proposed rule. We note that any proposals we would make on the formal validation process would be subject to public comment, and we would consider those comments before finalizing the policies.

3. Consolidating Reviews of Potentially Misvalued Codes

As previously discussed, we are statutorily required to review the RVUs of services paid under the PFS no less often than every 5 years. In the past, we have satisfied this requirement by conducting periodic reviews of work, PE, and malpractice RVUs for established services every 5 years in what is commonly known as CMS' Five-Year Reviews of Work, PE, and Malpractice RVUs. Recently, on May 24, 2011, we released the proposed notice regarding the Fourth Five-Year Review of Work RVUs. The most recent comprehensive Five-Year Review of PE RVUs occurred for CY 2010; the same year we began using the Physician Practice Information Survey (PPIS) data to update the PE RVUs. The last Five-Year Review of Malpractice RVUs also occurred for CY 2010. These Five-Year Reviews have historically included codes identified and nominated by the public for review, as well as those identified by CMS and the AMA RUC.

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 using various identification screens, such as codes with high growth rates, codes that are frequently billed together in one encounter, and codes that are valued as inpatient services but that are now predominately furnished as outpatient services. These annual reviews have not included codes identified by the public as potentially misvalued since historically, the public has the opportunity to submit potentially misvalued codes during the Five-Year Review process.

With the enactment of the Affordable Care Act in 2010, which endorsed our initiative to identify and review potentially misvalued codes and emphasized the importance of our ongoing work in this area to improve accuracy and appropriateness of payments under the PFS, we believe that continuing the annual identification and review of potentially misvalued codes is necessary. Given that we are engaging in extensive reviews of work RVUs and direct PE inputs of potentially misvalued codes on an annual basis, we believe that separate and ''freestanding'' Five-Year Reviews of Work and PE may have become redundant with our annual efforts. Therefore, for CY 2012 and forward, we propose to consolidate the formal Five-Year Review of Work and PE with the annual review of potentially misvalued codes. That is, we would begin meeting the statutory requirement to review work and PE RVUs for potentially misvalued codes at least once every 5 years through an annual process, rather than once every 5 years. Furthermore, to allow for public input and to preserve the public's ability to identify and nominate potentially misvalued codes for review, we are proposing a process by which the public could submit codes for our potential review, along with supporting documentation, on an annual basis. Our review of these codes would be incorporated into our potentially misvalued codes initiative. This proposal is further discussed in section II.B.4. of this proposed rule. We are soliciting comments on our proposal to consolidate the formal Five-Year Reviews of Work and PE with the annual review of potentially misvalued codes.

We note that while we are proposing to review the physician work RVUs and direct PE inputs of potentially misvalued codes on an annual basis, we are not proposing at this time to review malpractice RVUs on an annual basis. As discussed in section II.D. of this proposed rule, in general, malpractice RVUs are based on malpractice insurance premium data on a specialty level. The last comprehensive review and update of the malpractice RVUs occurred for CY 2010 using data obtained from the PPIS data. Since it is not feasible to conduct such extensive physician surveys to obtain updated specialty level malpractice insurance premium data on an annual basis, we believe the comprehensive review of malpractice RVUs should continue to occur at 5-year intervals.

Furthermore, in identifying and reviewing potentially misvalued codes on an annual basis, we note that this new proposed process presents us with the opportunity to review simultaneously both the work RVUs and the direct PE inputs, in conjunction, for each code. Heretofore, the work RVUs and direct PE inputs of potentially misvalued codes were commonly reviewed separately and at different times. For example, a code may have been identified as potentially misvalued based solely on its work RVUs so the AMA RUC would have reviewed the code and provided us with recommendations on the physician times and work RVUs. However, the code's direct PE inputs would not have necessarily been reviewed concurrently and therefore, the AMA RUC would not have necessarily provided us with recommendations for any changes in the direct PE inputs of the code that could have been necessary to ensure that the PE RVUs of the code are determined more appropriately. Therefore, while this code may have been recently reviewed and revised under the potentially misvalued codes initiative for physician work, the PE component of the code could still be potentially misvalued. Going forward, we believe combining the review of both physician work and PE for each code under our potentially misvalued codes initiative will more accurately align the review of these codes and lead to more accurate and appropriate payments under the PFS.

Finally, it is important to note that the code-specific resource based relative value framework under the PFS system is one in which services are ranked relative to each other. That is, the work RVUs assigned to a code are based on the physician time and intensity expended on that particular service as compared to the physician time and intensity of the other services paid under the PFS. This concept of relativity to other services also applies to the PE RVUs, particularly when it comes to reviewing and assigning correct direct PE inputs that are relative to other similar services. Consequently, we are emphasizing the need to review codes that are identified as part of the potentially misvalued initiative to ensure that appropriate relativity is constructed and maintained in several key relationships:

- The work and PE RVUs of codes are ranked appropriately within the code family. That is, the RVUs of services within a family should be ranked progressively so that less intensive services and/or services that require less physician time and/or require fewer or less expensive direct PE inputs should be assigned lower work or PE RVUs relative to other codes within the family. For example, if a code for treatment of elbow fracture is under review under the potentially misvalued

codes initiative, we would expect the work and PE RVUs for all the codes in the family also be reviewed in order to ensure that relativity is appropriately constructed and maintained within this family. Furthermore, as we noted in the CY 2010 PFS final rule with comment period (74 FR 61941), when we submit codes to the AMA RUC and request their review, in order to maintain relativity, we emphasized the importance of reviewing the base code of a family. The base code is the most important code to review because it is the basis for the valuation of other codes within the family and allows for all related codes to be reviewed at the same time (74 FR 61941).

- The work and PE RVUs of codes are appropriately relative based on comparison of physician time and/or intensity and/or direct inputs to other services furnished by physicians in the same specialty. To continue the example shown previously, if a code for treatment of elbow fracture is under review, we would expect this code to be compared to other codes, such as codes for treatment of humerus fracture, or other codes furnished by physicians in the same specialty, in order to ensure that the work and PE RVUs are appropriately relative within the specialty.
- The work and PE RVUs of codes are appropriately relative when compared to services across specialties. While it may be challenging to compare codes that describe completely unrelated services, since the entire PFS is a budget neutral system where payment differentials are dependent on the relative differences between services, it is essential that services across specialties are appropriately valued relative to each other. To illustrate the point, if a service furnished primarily by dermatology is analogous in physician time and intensity to another service furnished primarily by allergy/immunology, then we would expect the work RVUs for the two services to be similar, even though the two services may be otherwise unrelated.

4. Proposed Public Nomination Process

Under the previous Five-Year Reviews, the public was provided with the opportunity to nominate 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 are proposing a process by which on an annual basis the public could submit codes, along with documentation supporting the need for review. We are proposing that stakeholders may nominate potentially misvalued codes 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. We would evaluate the supporting documentation and decide whether the nominated code should be reviewed as potentially misvalued during the following year. If we were to receive an overwhelming number of nominated codes that qualified as potentially misvalued in any given year, we would prioritize the codes for review and could decide to hold our review of some of the potentially misvalued codes for a future year. We note that we may identify additional potentially misvalued codes for review by the AMA RUC based on the seven statutory categories under section 1848(c)(2)(K)(ii) of the Act.

We encourage stakeholders who believe they have identified a potentially misvalued code, supported by documentation, to nominate codes through the public process. We emphasize that in order to ensure that a nominated code will be fully considered to qualify as a potentially misvalued code to be reviewed under our annual process, accompanying documentation must be provided to show evidence of the code's inappropriate valuation, either in terms of inappropriate physician times, work RVUs, and/or direct PE inputs. The AMA RUC developed certain ''Guidelines for Compelling Evidence'' for the Third Five-Year Review which we believe could be applicable for members of the public as they gather supporting documentation for codes they wish to publicly nominated for the annual review of potentially misvalued codes. The specific documentation that we would seek under this proposal includes 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.
  - ++ Physician time.
- An anomalous relationship between the code being proposed for review and other codes. For example, if code ''A'' describes a service that requires more work than codes ''B,'' ''C,'' and ''D,'' but is nevertheless valued lower. The commenter would need to assemble evidence on service time, technical skill, patient severity, complexity, length of stay and other factors for the code being considered and the codes to which it is compared. These reference services may be both inter- and intra-specialty.
- 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 Initiative (PQRI) databases).
- National surveys of physician time and intensity from professional and management societies and organizations, such as hospital associations.

We note that when a code is nominated, and supporting documentation is provided, we would expect to receive a description of the reasons for the code's misvaluation with the submitted materials. That is, we would require a description and summary of the evidence is required that shows how the service may have changed since the original valuation or may have been inappropriately valued due to an incorrect assumption. We would also appreciate specific **Federal Register** citations, if they exist, where commenters believe the nominated codes were previously valued erroneously. We are also proposing to consider only nominations of active codes that are covered by Medicare at the time of the nomination.

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 intend to review the supporting documentation and determine whether they appear to be potentially misvalued codes appropriate for review under the annual process. We are proposing that, in the following PFS proposed rule, we would publish a list of the codes received under the public nomination process during the previous year and

indicate whether the codes would be included in our annual review of potentially misvalued codes. We would also indicate the codes that we would not be including in our annual review, whether due to insufficient documentation or for other reasons. Under this proposed process, the first opportunity for the public to nominate codes would be during the public comment period for the CY 2012 PFS final rule with comment period. We would publish in the CY 2013 PFS proposed rule, the list of nominated codes, and whether they will be reviewed as potentially misvalued codes. We would request the AMA RUC review these potentially misvalued codes identified by the public, along with any other codes identified by us, and provide to us recommendations for appropriate physician times, work RVUs, and direct PE inputs. We are soliciting public comments on this proposed code nomination process and we will consider any suggestions to modify and improve the proposed process.

5. CY 2012 Identification and Review of Potentially Misvalued Services

a. Code Lists

While we anticipate receiving nominations from the public for potentially misvalued codes in conjunction with rulemaking, we believe it is imperative that we continue the work of the review initiatives over the last several years and drive the agenda forward to identify, review, and adjust values for potentially misvalued codes for CY 2012.

In the CY 2011 PFS proposed rule (75 FR 40068 through 40069), we identified, and referred to the AMA RUC, a list of potentially misvalued codes in three areas:

- Codes on the AMA RUC's multi-specialty points of comparison (MPC) list (used as reference codes in the valuation of other codes),
- Services with low work RVUs that are billed in multiples (a statutory category); and
- Codes that have low work RVUs for which CMS claims data show high volume (that is, high utilization of these codes represents a significant dollar impact in the payment system).

Our understanding is that the AMA RUC is currently working towards reviewing these codes at our request. We intend to provide an update and discuss any RVU adjustments to codes that have been identified as potentially misvalued in the CY 2012 PFS final rule, as they move through the review process.

Meanwhile, for CY 2012, we are continuing with the work to identify and review additional services under the potentially misvalued codes initiative. Stakeholders have noted that many of the services previously identified under the potentially misvalued codes initiative were concentrated in certain specialties. To develop a robust and representative list of codes for review under the potentially misvalued codes initiative, we examined the highest PFS expenditure services by specialty (based on our most recently available claims data and using the specialty categories listed in the PFS specialty impact table, see Table 64 in section VII.B. of this proposed rule) and identified those that have not been reviewed since CY 2006 (which was the year we completed the Third Five-Year Review of Work and before we began our potentially misvalued codes initiative).

In our examination of the highest PFS expenditure codes for each specialty (we used the specialty categories listed in the PFS specialty impact table, see Table 64 in section VII.B. of this proposed rule), we noted that E/M services consistently appeared in the top 20 high PFS expenditure services. We noted as well that most of the E/M services have not been reviewed since the comprehensive review of services for the Third Five-Year Review of Work in CY 2006. Therefore, after an examination of the highest PFS expenditure codes for each specialty, we have developed two code lists of potentially misvalued codes which we are proposing to refer to the AMA RUC for review.

First, we are requesting that the AMA RUC conduct a comprehensive review of all E/M codes, including the codes listed in Table 6. During the intervening years, there has been significant interest in delivery system reform, such as patient-centered medical homes and making the primary care physician the focus of managing the patient's chronic conditions. The chronic conditions challenging the Medicare population include heart disease, diabetes, respiratory disease, breast cancer, allergy, Alzheimer's disease, and factors associated with obesity. Thus, as the focus of primary care has evolved from an episodic treatment-based orientation to a focus on comprehensive patient-centered care management in order to meet the challenges of preventing and managing chronic disease, we believe a more current review of E/M codes is warranted. We note that although physicians in primary care specialties bill a high percentage of their services using the E/M codes, physicians in non-primary care specialties also bill these codes for some of their services.

Since we believe the focus of primary care has evolved to meet the challenges of preventing and managing chronic disease since the last comprehensive review of the E/M codes, we would like the AMA RUC to prioritize review of the E/M codes and provide us with recommendations on the physician times, work RVUs and direct PE inputs of at least half of the E/M codes listed in Table 6 by July 2012 in order for us to include any revised valuations for these codes in the CY 2013 PFS final rule with comment period. We would expect the AMA RUC to review the remaining E/M codes listed in Table 6 by July 2013 in order for us to complete the comprehensive re-evaluation of E/M services and include the revised valuations for these codes in the CY 2014 PFS final rule with comment period.

TABLE 6—E/M CODES REFERRED FOR AMA RUC REVIEW

CPT Code	Short descriptor
99201	Office/outpatient visit new
99202	Office/outpatient visit new
99203	Office/outpatient visit new
99204	Office/outpatient visit new
99205	Office/outpatient visit new
99211	Office/outpatient visit est
99212	Office/outpatient visit est
99213	Office/outpatient visit est
99214	Office/outpatient visit est
99215	Office/outpatient visit est
99217	Observation care discharge
99218	Initial observation care
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care
99223	Initial hospital care
99224	Subsequent observation care
99225	Subsequent observation care
99226	Subsequent observation care
99231	Subsequent hospital care
99232	Subsequent hospital care
99233	Subsequent hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99238	Hospital discharge day
99239	Hospital discharge day
99281	Emergency dept visit
99282	Emergency dept visit
99283	Emergency dept visit
99284	Emergency dept visit
99285	Emergency dept visit
99291	Critical care first hour
99292	Critical care addl 30 min
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99307	Nursing fac care subseq
99308	Nursing fac care subseq
99309	Nursing fac care subseq
99310	Nursing fac care subseq

TABLE 6—E/M CODES REFERRED FOR AMA RUC REVIEW—Continued

CPT Code	Short descriptor
99315	Nursing fac discharge day
99316	Nursing fac discharge day
99318	Annual nursing fac assessmnt
99324	Domicil/r-home visit new pat
99325	Domicil/r-home visit new pat
99326	Domicil/r-home visit new pat
99327	Domicil/r-home visit new pat
99328	Domicil/r-home visit new pat
99334	Domicil/r-home visit est pat
99335	Domicil/r-home visit est pat
99336	Domicil/r-home visit est pat
99337	Domicil/r-home visit est pat
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient
99344	Home visit new patient
99345	Home visit new patient
99347	Home visit est patient
99348	Home visit est patient
99349	Home visit est patient
99350	Home visit est patient
99354	Prolonged service office
99355	Prolonged service office
99356	Prolonged service inpatient
99357	Prolonged service inpatient
99406	Behav chng smoking 3–10 min
99407	Behav chng smoking > 10 min
99460	Init nb em per day hosp
99461	Init nb em per day non-fac
99462	Sbsq nb em per day hosp
99463	Same day nb discharge
99464	Attendance at delivery
99465	Nb resuscitation
99466	Ped crit care transport
99467	Ped crit care transport addl
99468	Neonate crit care initial
99469	Neonate crit care subsq
99471	Ped critical care initial
99472	Ped critical care subsq
99475	Ped crit care age 2–5 init
99476	Ped crit care age 2–5 subsq
99477	Init day hosp neonate care
99478	Ic lbw inf < 1500 gm subsq
99479	Ic lbw inf 1500–2500 g subsq
99480	Ic inf pbw 2501–5000 g subsq
92002	Eye exam new patient
92004	Eye exam new patient
92012	Eye exam established pat
92014	Eye exam & treatment

Second, we are also providing a select list of high PFS expenditure procedural codes representing services furnished by an array of specialties, as listed in Table 7. These procedural codes have not been reviewed since CY 2006 (before we began our potentially misvalued codes initiatives in CY 2008) and, based on the most recently available data, have CY 2010 allowed charges of greater than $10 million at the specialty level (based on the specialty categories listed in the PFS specialty impact table and CY 2010 Medicare claims data). A number of the codes in Table 7 would not otherwise be identified as potentially misvalued services using the screens we have used in recent years with the AMA RUC or based on one of the six specific statutory categories under section 1848(c)(2)(k)(ii) of the Act. However, we identified the potentially misvalued codes listed in Table 7 under the seventh statutory category, ''other codes determined to be appropriate by the Secretary.'' We selected these codes based on the fact that they have not been reviewed for at least 6 years, and in many cases the last review occurred more than 10 years ago. They represent high Medicare expenditures under the PFS; thus, we believe that a review to assess changes in physician work and update direct PE inputs is warranted. Furthermore, since these codes have significant impact on PFS payment on a specialty level, a review of the relativity of the code to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties, as discussed previously, is essential. For these reasons, we have identified these codes as potentially misvalued and are requesting that the AMA RUC review the codes listed in Table 7 and provide us with recommendations on the physician times, work RVUs and direct PE inputs in a timely manner. That is, similar to our request for the AMA RUC to review E/M codes in a timely manner, we are requesting that the AMA RUC review at least half of the procedural codes listed in Table 7 by July 2012 in order for us to include any revised valuations for these codes in the CY 2013 PFS final rule with comment period.

TABLE 7—SELECT LIST OF PROCEDURAL CODES REFERRED FOR AMA RUC REVIEW

CPT Code	Short descriptor
95117	Immunotherapy Injections
33533	Cabg, Arterial, Single
33405	Replacement Of Aortic Valve
33430	Replacement Of Mitral Valve
93015	Cardiovascular Stress Test
93880	Extracranial Study
93000	Electrocardiogram, Complete
17311	Mohs, 1 Stage, H/N/Hf/G
17312	Mohs Addl Stage
17004	Destroy Premlg Lesions 15+
45378	Diagnostic Colonoscopy
43235	Uppr Gi Endoscopy, Diagnosis
47562	Laparoscopic Cholecystectomy
47563	Laparo Cholecystectomy/Graph
49505	Prp I/Hern Init Reduc > 5 Yr
96413	Chemo, Iv Infusion, 1 Hr
96367	Tx/Proph/Dg Addl Seq Iv Inf
96365	Ther/Proph/Diag Iv Inf, Init
62311	Inject Spine L/S (Cd)
35476	Repair Venous Blockage
36870	Percut Thrombect Av Fistula
35475	Repair Arterial Blockage
95903	Motor Nerve Conduction Test
95819	Eeg, Awake And Asleep
95861	Muscle Test, 2 Limbs
22612	Lumbar Spine Fusion
63047	Removal Of Spinal Lamina
22851	Apply Spine Prosth Device
76830	Transvaginal Us, Non-Ob
67028	Injection Eye Drug
92235	Eye Exam With Photos
66982	Cataract Surgery, Complex
27447	Total Knee Arthroplasty
27130	Total Hip Arthroplasty
27236	Treat Thigh Fracture
69210	Remove Impacted Ear Wax
31237	Nasal/Sinus Endoscopy, Surg
88342	Immunohistochemistry
88112	Cytopath, Cell Enhance Tech
88312	Special Stains Group 1
97140	Manual Therapy
90862	Medication Management
90801	Psy Dx Interview
90805	Psytx, Off, 20-30 Min W/E&M
94720	Monoxide Diffusing Capacity
94240	Residual Lung Capacity
77014	Ct Scan For Therapy Guide
77301	Radiotherapy Dose Plan, Imrt
77421	Stereoscopic X-Ray Guidance
70450	Ct Head/Brain W/O Dye
70553	Mri Brain W/O & W/Dye
72148	Mri Lumbar Spine W/O Dye
20610	Drain/Inject, Joint/Bursa
53850	Prostatic Microwave Thermotx
50590	Fragmenting Of Kidney Stone
76872	Us, Transrectal
35301	Rechanneling Of Artery
98941	Chiropractic Manipulation
98940	Chiropractic Manipulation
98942	Chiropractic Manipulation
90806	Psytx, Off, 45–50 Min
90818	Psytx, Hosp, 45–50 Min
90808	Psytx, Office, 75–80 Min
72141	Mri Neck Spine W/O Dye
73221	Mri Joint Upr Extrem W/O Dye
70551	Mri Brain W/O Dye
92083	Visual Field Examination(S)
97530	Therapeutic Activities
97112	Neuromuscular Reeducation
97001	Pt Evaluation

b. Specific Codes

On an ongoing basis, public stakeholders (including physician specialty societies, beneficiaries, and other members of the public) bring concerns to us regarding direct PE inputs and physician work. In the past, we would consider these concerns and address them through proposals in annual rulemaking, technical corrections, or by requesting that the AMA RUC consider the issue.

Since last year's rulemaking, the public has brought a series of issues to our attention that relate directly to direct PE inputs and physician work. We believe that some of these issues will serve as examples of codes that might be brought forward by the public

as potentially misvalued in the proposed nomination process as discussed previously in section II.B.4. of this proposed rule.

(1) Codes Potentially Requiring Updates to Direct PE Inputs

Abdomen and Pelvis CT. For CY 2011, AMA CPT created a series of new codes that describe combined CTs of the abdomen and pelvis. Prior to 2011, these services would have been billed using multiple stand-alone codes for each body region. The new codes are: 74176 (Computed tomography, abdomen and pelvis; without contrast material); 74177 (Computed tomography, abdomen and pelvis; with contrast material); and 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions.)

As stated in the CY 2011 PFS final rule with comment period (75 FR 73350), we accepted the AMA RUC-recommended direct PE inputs for these codes, with refinements to the equipment minutes to assure that the time associated with the equipment items reflected the time during the intra-service period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. We believe that the direct PE inputs of the new codes reflect the typical resources required to furnish the services in question.

However, stakeholders have alerted us that the resulting PE RVUs for the new codes reflect an anomalous rank order in comparison to the previously existing stand-alone codes. Specifically, the PE RVUs for the codes that describe CT scans without contrast for either body region are greater than the PE RVUs for 74176, which describes a CT scan of both body regions. We believe that the anomalous rank order of the PE RVUs for this series of codes may be the result of outdated direct PE inputs for the previously existing stand-alone codes. The physician work for those codes was last reviewed by the AMA RUC during the Third Five-Year Review of Work for CY 2007. However, the direct PE inputs for the codes have not been reviewed since 2003. Therefore, we are requesting that the AMA RUC review both the direct PE inputs and work values of the following codes in accordance with the consolidated approach to reviewing potentially misvalued codes as outlined in section II.B.2.c. of this proposed rule:

- 72192 Computed tomography, pelvis; without contrast material
- 72193 Computed tomography, pelvis; with contrast material(s)
- 72194 Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections
- 74150 Computed tomography, abdomen; without contrast material
- 74160 Computed tomography, abdomen; with contrast material(s)
- 74170 Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections

Tissue Pathology. A stakeholder informed us that the direct PE inputs associated with a particular tissue examination code are atypical. Specifically, the stakeholder suggested that the AMA RUC relied upon an atypical clinical vignette in identifying the direct PE inputs for the service associated with CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination Abortion—spontaneous/missed, Artery, biopsy, Bone marrow, biopsy, Bone exostosis, Brain/meninges, other than for tumor resection, Breast, biopsy, not requiring microscopic evaluation of surgical margins, Breast, reduction mammoplasty, Bronchus, biopsy, Cell block, any source, Cervix, biopsy, Colon, biopsy, Duodenum, biopsy, Endocervix, curettings/biopsy, Endometrium, curettings/biopsy, Esophagus, biopsy, Extremity, amputation, traumatic, Fallopian tube, biopsy, Fallopian tube, ectopic pregnancy, Femoral head, fracture, Fingers/toes, amputation, non-traumatic, Gingiva/oral mucosa, biopsy, Heart valve, Joint, resection, Kidney, biopsy, Larynx, biopsy, Leiomyoma(s), uterine myomectomy—without uterus, Lip, biopsy/wedge resection, Lung, transbronchial biopsy, Lymph node, biopsy, Muscle, biopsy, Nasal mucosa, biopsy, Nasopharynx/oropharynx, biopsy, Nerve, biopsy, Odontogenic/dental cyst, Omentum, biopsy, Ovary with or without tube, non-neoplastic, Ovary, biopsy/wedge resection, Parathyroid gland, Peritoneum, biopsy, Pituitary tumor, Placenta, other than third trimester, Pleura/pericardium—biopsy/tissue, Polyp, cervical/endometrial, Polyp, colorectal, Polyp, stomach/small intestine, Prostate, needle biopsy, Prostate, TUR, Salivary gland, biopsy, Sinus, paranasal biopsy, Skin, other than cyst/tag/debridement/plastic repair, Small intestine, biopsy, Soft tissue, other than tumor/mass/lipoma/debridement, Spleen, Stomach, biopsy, Synovium, Testis, other than tumor/biopsy/castration, Thyroglossal duct/brachial cleft cyst, Tongue, biopsy, Tonsil, biopsy, Trachea, biopsy, Ureter, biopsy, Urethra, biopsy, Urinary bladder, biopsy, Uterus, with or without tubes and ovaries, for prolapse, Vagina, biopsy, Vulva/labia, biopsy).

The stakeholder claims that in furnishing the typical service, the required material includes a single block of tissue and 1–3 slides. The stakeholder argues that the typical costs for the service amount is approximately $18, but the PE RVUs for 2011 result in a national payment rate of $69.65 for the technical component of the service. Because the direct PE inputs associated with this code have not been reviewed since 1999, we are asking that the AMA RUC review both the direct PE inputs and work values of this code as soon as possible in accordance with the consolidated approach to reviewing potentially misvlaued codes as outlined in section II.B.2.c. of this proposed rule though the work for this code was reviewed in April 2010.

In Situ Hybridization Testing. We received comments from the Large Urology Group Practice Association (LUGPA) regarding two new cytopathology codes that describe in situ hybridization testing of urine specimens. Prior to CY 2011, all in situ hybridization testing was coded and billed using CPT Codes 88365 (In situ hybridization (eg, FISH), each probe), 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology) and 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual). The appropriate CPT code listed would be billed one time for each probe used in the performance of the test, regardless of the medium of the specimen (that is, blood, tissue, tumor, bone marrow or urine).

For CY 2011, the AMA's CPT Editorial Panel created two new cytopathology codes that describe in situ hybridization testing using urine samples: CPT code 88120 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) and CPT code 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology).

Because the descriptors indicate that the new codes account for approximately 4 probes, whereas 88367 and 88368 describe each probe, there are more PE RVUs associated with the new codes than with the previously existing codes that are currently still used for any specimen except for urine.

However, because the previously existing codes are billed per probe, the payment for a test using a different specimen type could vary depending upon the number of probes. For example, a practitioner furnishing a test involving a blood specimen and using two probes would bill CPT code 88368 (total RVUs: 6.28) three times with the result of 18.84 RVUs. A practitioner furnishing the same test but using a urine sample instead of a blood sample would receive payment based on the 13.47 RVUs associated with CPT code 88120.

CMS accepted the RUC-recommended work values and direct PE inputs, without refinement, for the two new cytopathology codes that describe in situ hybridization testing using urine samples. We have reviewed the direct PE recommendations made by the AMA RUC and, at this time, believe that these inputs are appropriate.

However, we share LUGPA's concerns regarding the potential payment discrepancies between the codes that describe the same test using different specimen media. Therefore, we are asking the AMA RUC to review the both the direct PE inputs and work values of the following codes in accordance with the consolidated approach to reviewing potentially misvlaued codes as outlined in section II.B.2.c. of this proposed rule: CPT codes 88365 (In situ hybridization (e.g., FISH), each probe); 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology); and 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual.)

(2) Codes Without Direct Practice Expense Inputs in the Non-Facility Setting

Certain stakeholders have requested that we create nonfacility PE values for a series of kyphoplasty services CPT codes:

- 22523 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic),
- 22524 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); lumbar).
- 22525 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure).

In the case of these codes, we are asking the RUC to make recommendations regarding the appropriateness of creating nonfacility direct PE inputs. If the RUC were to recommend direct PE recommendations, we would review those recommendations as part of the annual process.

Ultrasound Equipment. A stakeholder has raised concern about potential inconsistencies with the inputs and the prices related to ultrasound equipment in the direct PE database. Upon reviewing inputs and prices for ultrasound equipment, we have noted that there are 17 different pieces of ultrasound and ultrasound-related equipment in the database that are associated with 110 CPT Codes. The price inputs for ultrasound equipment range from $1,304.33 to $466,492.00. Therefore, we are asking the AMA RUC to review the ultrasound equipment included in those codes as well as how the way the equipment is described and priced in the direct PE database.

In the past, the AMA RUC has provided us with valuable recommendations regarding particular categories of equipment and supply items that are used as direct PE inputs for a range of codes. For example, in the 2011 PFS final rule (75 FR 73204), we made changes to a series of codes following the RUC's review of services that include the radiographic fluoroscopic room (CMS Equipment Code EL014) as a direct PE input. The RUC review revealed the use of the item to no longer be typical for certain services in which it had been specified within the direct cost inputs. These recommendations have often prompted our proposals that have served to maintain appropriate relativity within the PFS, and we hope that the RUC will continue to address issues relating to equipment and supply inputs that affect many codes. Furthermore, we believe that in these kinds of cases, it may be appropriate to make changes to the related direct PE inputs for a series of codes without reevaluating the physician work or other direct PE inputs for the individual codes. In other words, while we generally believe that both the work and the direct practice expense inputs should be reviewed whenever the RUC makes recommendations regarding either component of a code's value, we recognize the value of discrete RUC reviews of direct PE items that serve as inputs for a series of service codes.

(3) Codes Potentially Requiring Updates to Physician Work

Cholecystectomy. We received a comment regarding a potential relativity problem between two cholecystectomy (gall bladder removal) CPT codes. CPT code 47600 (Cholecystectomy;) has a work RVU of 17.48, and CPT code 47605 (Cholecystectomy; with cholangiography) has a work RVU of 15.98. Upon examination of the physician time and visits associated with these codes, we found that CPT code 47600 includes 115 minutes of intra-service time and a total time of 420 minutes, including 3 office visits, 3 subsequent hospital care days, and 1 hospital discharge management day. CPT code 47605 includes 90 minutes of intra-service time and a total time of 387 minutes, including 2 office visits, 3 subsequent hospital care days, and 1 hospital discharge management day. We believe that the difference in physician time and visits is the cause for the difference in work RVU for these codes. However, upon clinical review, it does not appear that these visits appropriately reflect the relativity of these two services, as CPT code 47600 should not have more time and visits associated with the service than CPT code 47605. Therefore, we are asking the AMA RUC to review these two cholecystectomy CPT codes, 47600 and 47605.

We thank the public for bringing these issues to our attention and kindly request that the public continue to do so. Please see section II.B.4. of this proposed notice for more information on the proposed public process for the nomination of potentially misvalued codes.

6. Code-Specific Issues

a. CY 2012 Codes With Site-of-Service Anomalies

(1) Background

The AMA RUC reviewed a number of site-of-service anomaly codes for CY 2012, many of which are site-of-service anomaly codes that have had interim values in place since CY 2009. These are CPT codes that have experienced a change in the typical site-of-service since the original valuation of the codes. Specifically, these codes were originally furnished in the inpatient setting, but Medicare claims data show that the typical case has shifted to being furnished in the outpatient setting. Since the procedures were typically furnished in the inpatient setting when the codes were originally valued, the work RVUs for these codes would have

been valued to include the inpatient physician work furnished, as well as to reflect the intensive follow-up care normally associated with an inpatient procedure. As we discussed in the CY 2011 final rule with comment period (75 FR 73221), when the typical case for a service has shifted from the inpatient setting to an outpatient or physician's office setting, we do not believe the inclusion of inpatient hospital visits in the post-operative period is appropriate. For example, inpatient E/M visit codes such as CPT codes 99231 (Level 1 subsequent hospital care, per day); 99232 (Level 2 subsequent hospital care, per day); and 99233 (Level 3 subsequent hospital care, per day), should not be included in the valuation of these services. Additionally, we believe that it is reasonable to expect that there have been changes in medical practice for these services, and that such changes would represent a decrease in physician time or intensity or both. The AMA RUC reviewed 40 CPT codes that were identified as having site-of-service anomalies and recommended revised RVUs to CMS for 29 codes for CY 2009 and 11 codes for CY 2010. In the CY 2010 PFS proposed rule and final rule with comment period (74 FR 33556 and 74 FR 61777, respectively), we encouraged the AMA RUC to utilize the building block methodology when revaluing services with site-of-service anomalies. In the CY 2011 PFS final rule with comment period (75 FR 73221), we also stated that in the CYs 2009 and 2010 PFS final rules with comment period (73 FR 69883 and 74 FR 61776 through 61778, respectively), we indicated that although we would accept the AMA RUC valuations for these site-of-service anomaly codes on an interim basis through CY 2010, we had ongoing concerns about the methodology used by the AMA RUC to value these services. We requested that the AMA RUC re-examine the site-of-service anomaly codes and adjust the work RVU, time, and post-service visits to reflect those typical of a service furnished in an outpatient or physician's office setting.

Following our request in the CY 2011 PFS final rule with comment period, the AMA RUC re-reviewed these site-of-service anomaly codes and recommended work RVUs to us. Of the 40 CPT codes on the CY 2009 and CY 2010 site-of-service anomaly code lists in the CY 2011 PFS final rule with comment period, 1 CPT code was not re-reviewed, as it was addressed in the CY 2011 PFS final rule with comment period as a part of the vagal nerve stimulator family of services. Ten of the remaining 39 site-of-service anomaly codes were addressed in the Five-Year Review of Work, published in the **Federal Register** on June 6, 2011 (76 FR 32410). The remaining 29 CPT codes are addressed in this CY 2012 PFS proposed rule. We will summarize and respond to public comments, and adopt final work RVUs for all 40 CPT codes on the CY 2009 and CY 2010 site-of-service anomaly lists in the CY 2012 PFS final rule with comment period. In addition, several other CPT codes have since been identified as having site-of-service anomalies and were addressed in the Five-Year Review of Work (76 FR 32410). We will respond to public comments and adopt final work values for these codes in the CY 2012 PFS final rule with comment period. A complete list of the 40 CPT codes with site-of-service anomalies identified in CY 2009 and CY 2010, the rule in which each code was addressed, the AMA RUC-recommended work RVU, and the CMS proposed or interim work RVU can be found in Table 8.

When Medicare claims data show that the typical setting for a CPT code has shifted from the inpatient setting to the outpatient setting, we continue to believe that the work RVU, time, and post-service visits of the code should reflect the current outpatient setting. For many of the site-of-service anomaly CPT codes, we believe that the AMA RUC appropriately accounted for this site-of-service shift in its recommendations to us, and we agree with the AMA RUC-recommended work RVU for 19 of the 40 CY 2009 and CY 2010 site-of-service anomaly codes. However, we found that for the remainder of these site-of-service anomaly codes (21 of 40), the AMA RUC often recommended maintaining inpatient visits or removing inpatient visits and/or time without a corresponding decrease in work RVU. In those cases, we disagreed with the AMA RUC-recommended work RVU and adjusted the work RVU, time, and visits to reflect those typical of a service furnished in an outpatient or physician's office setting. In the Fourth Five-Year Review of Work (76 FR 32410), we discussed in detail our methodology for revaluing the site-of-service anomaly codes addressed in that proposed notice. We continue that discussion here, and a full description of our methodology for revaluing the site-of-service anomaly codes for CY 2012 is included later in this section.

TABLE 8—CMS DECISIONS ON CODES WITH SITE-OF-SERVICE ANOMALIES

CPT Code	Short descriptor	CMS Work RVU decision publication	AMA RUC Rec-ommended work RVU	CMS Work RVU decision	CMS Proposed/ interim Work RVU
21025	Excision of bone, lower jaw	CY 2012 PFS NPRM	10.03	Agree	10.03
23415	Release of shoulder ligament	CY 2012 PFS NPRM	9.23	Agree	9.23
25116	Remove wrist/forearm lesion	CY 2012 PFS NPRM	7.56	Agree	7.56
28120	Part removal of ankle/heel	Fourth Five-Year Review of Work	8.27	Disagree	7.31
28122	Partial removal of foot bone	Fourth Five-Year Review of Work	7.72	Disagree	6.76
28725	Fusion of foot bones	CY 2012 PFS NPRM	12.18	Disagree	11.22
28730	Fusion of foot bones	CY 2012 PFS NPRM	12.42	Disagree	10.70
36825	Artery-vein autograft	Fourth Five-Year Review of Work	15.13	Disagree	14.17
42415	Excise parotid gland/lesion	Fourth Five-Year Review of Work	18.12	Disagree	17.16
42420	Excise parotid gland/lesion	Fourth Five-Year Review of Work	21.00	Disagree	19.53
42440	Excise submaxillary gland	CY 2012 PFS NPRM	7.13	Disagree	6.14
49507	Prp i/hern init block >5 yr	Fourth Five-Year Review of Work	10.05	Disagree	9.09
49521	Rerepair ing hernia, blocked	Fourth Five-Year Review of Work	12.44	Disagree	11.48
49587	Rpr umbil hern, block > 5 yr	Fourth Five-Year Review of Work	8.04	Disagree	7.08
52341	Cysto w/ureter stricture tx	CY 2012 PFS NPRM	5.35	Agree	5.35
52342	Cysto w/up stricture tx	CY 2012 PFS NPRM	5.85	Agree	5.85
52343	Cysto w/renal stricture tx	CY 2012 PFS NPRM	6.55	Agree	6.55
52344	Cysto/uretero, stricture tx	CY 2012 PFS NPRM	7.05	Agree	7.05
52345	Cysto/uretero w/up stricture	CY 2012 PFS NPRM	7.55	Agree	7.55

TABLE 8—CMS DECISIONS ON CODES WITH SITE-OF-SERVICE ANOMALIES—Continued

CPT Code	Short descriptor	CMS Work RVU decision publication	AMA RUC Rec-ommended work RVU	CMS Work RVU decision	CMS Proposed/ interim Work RVU
52346	Cystouretero w/renal strict	CY 2012 PFS NPRM	8.58	Agree	8.58
52400	Cystouretero w/congen repr	CY 2012 PFS NPRM	8.69	Agree	8.69
52500	Revision of bladder neck	CY 2012 PFS NPRM	8.14	Agree	8.14
52640	Relieve bladder contracture	Fourth Five-Year Review of Work	4.79	Agree	4.79
53445	Insert uro/ves nck sphincter	CY 2012 PFS NPRM	15.39	Disagree	13.00
54410	Remove/replace penis prosth	CY 2012 PFS NPRM	15.18	Agree	15.18
54530	Removal of testis	CY 2012 PFS NPRM	8.46	Agree	8.46
57287	Revise/remove sling repair	Fourth Five-Year Review of Work	11.15	Agree	11.15
61885	Insrt/redo neurostim 1 array	CY 2011 PFS Final Rule	6.44	Disagree	6.05
62263	Epidural lysis mult sessions	CY 2012 PFS NPRM	6.54	Disagree	5.00
62350	Implant spinal canal cath	CY 2012 PFS NPRM	6.05	Agree	6.05
62355	Remove spinal canal catheter	CY 2012 PFS NPRM	4.35	Disagree	3.55
62360	Insert spine infusion device	CY 2012 PFS NPRM	4.33	Agree	4.33
62361	Implant spine infusion pump	CY 2012 PFS NPRM	5.65	Disagree	5.00
62362	Implant spine infusion pump	CY 2012 PFS NPRM	6.10	Disagree	5.60
62365	Remove spine infusion device	CY 2012 PFS NPRM	4.65	Disagree	3.93
63650	Implant neuroelectrodes	CY 2012 PFS NPRM	7.20	Disagree	7.15
63685	Insrt/redo spine n generator	CY 2012 PFS NPRM	6.05	Disagree	5.19
64708	Revise arm/leg nerve	CY 2012 PFS NPRM	6.36	Agree	6.36
64831	Repair of digit nerve	CY 2012 PFS NPRM	9.16	Agree	9.16
65285	Repair of eye wound	CY 2012 PFS NPRM	16.00	Disagree	15.36

(2) Revised Work RVUs for Codes With Site-of-Service Anomalies

(A) Foot Arthrodesis

CPT Code	Short descriptor	AMA RUC Rec-ommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
28725	Fusion of foot bones	12.18	Disagree	11.22
28730	Fusion of foot bones	12.42	Disagree	10.70

For CPT code 28725 (Arthrodesis; subtalar) and 28730 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse) the most recently available Medicare claims data suggests that these site-of-service anomaly codes could be ''23-hour stay'' outpatient services. As we discussed in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227) and the Five-Year Review of Work (76 FR 32410), the ''23-hour stay service'' is a term of art describing services that typically have lengthy hospital outpatient recovery periods. For these 23-hour stay services, the typical patient is commonly at the hospital for less than 24-hours, but often stays overnight at the hospital. Unless a treating physician has written an order to admit the patient as an inpatient, the patient is considered for Medicare purposes to be a hospital outpatient, not an inpatient, and our claims data support that the typical 23-hour stay service is billed as an outpatient service.

As we discussed in the Five-Year Review of Work (76 FR 32410), we believe that the values of the codes that fall into the 23-hour stay category should not reflect work that is typically associated with an inpatient service. However, as we stated in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227), we find it is plausible that while the patient receiving the outpatient 23-hour stay service remains a hospital outpatient, the patient would typically be cared for by a physician during that lengthy recovery period at the hospital. While we do not believe that post-procedure hospital visits would be at the inpatient level since the typical case is an outpatient who would be ready to be discharged from the hospital in 23-hours or less, we believe it is generally appropriate to include the intra-service time of the inpatient hospital visit in the immediate post-service time of the 23-hour stay code under review. In addition, we indicated that we believe it is appropriate to include a half day, rather than a full day, of a discharge day management service. We finalized this policy in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227) and encouraged the AMA RUC to apply this methodology in developing the recommendations it provides to us for valuing 23-hour stay codes, in order to ensure the consistent and appropriate valuation of the physician work for these services.

For CY 2010, CPT codes 28725 and 28730 were identified as potentially misvalued through the site-of-service anomaly screen and were reviewed by the AMA RUC. For both of these services, based on reference services and specialty survey data, the AMA RUC recommended maintaining the current (CY 2009) work RVU, which we then increased slightly based on the redistribution of RVUs that resulted from the CY 2010 policy to no longer recognize the CPT consultation codes (74 FR 61775). The AMA RUC re-reviewed CPT codes 28725 and 28730 for CY 2012 and, contrary to the 23-hour stay policy we finalized in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227), recommended replacing the hospital inpatient post-operative visit in the

current work values with a subsequent observation care service, specifically CPT code 99224 (Level 1 subsequent observation care, per day) and recommended maintaining the current interim value of the two CPT codes. Specifically, for CY 2012 the AMA RUC recommended a work RVU of 12.18 for CPT code 28725 and a work RVU of 12.42 for CPT code 28730.

We disagree with the AMA RUC-recommended values for CPT codes 28725 and 28730. We believe the appropriate methodology for valuing these codes entails accounting for the removal of the inpatient visits in the work value for the site-of-service anomaly codes since these services are no longer typically furnished in the inpatient setting. We do not believe it is appropriate to simply exchange the inpatient post-operative visits in the original value with subsequent observation care visits and maintain the current work RVUs.

As the data suggests, these two site-of-service anomaly codes resemble 23-hour stay outpatient services, and since the AMA RUC's recommended value continues to include inpatient visits (or subsequent observation care codes) in the post-operative period, we applied the 23-hour stay policy described previously. Specifically, we removed the subsequent observation care service, reduced the one day of discharge management service to one-half day, and adjusted physician work RVUs and times accordingly. As a result, for CY 2012 we are proposing a work RVU of 11.22 for CPT code 28725, and a work RVU of 10.70 for CPT code 28730, with aforementioned refinements to time. A complete list of CMS time refinements can be found in Table 9.

(B) Submandibular Gland Excision

CPT Code	Short descriptor	AMA RUC Rec-ommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
42440	Excise submaxillary gland	7.13	Disagree	6.14

For CY 2009, CPT code 42440 (Excision of submandibular (submaxillary) gland) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended maintaining the current (CY 2008) work RVU of 7.05 for this service and removing the inpatient subsequent hospital care visit blocks to reflect the current outpatient place of service. In CY 2010, while CMS adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 42440 used under the PFS was increased to 7.13 based on the redistribution of RVUs that resulted from our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC resubmitted its previous recommendation and again recommended that the current work RVU of 7.13 for CPT code 42440 be maintained.

We disagree with the AMA RUC-recommended work RVU of 7.13 for CPT code 42440 and believe a work RVU of 6.14 is more appropriate for this service. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. To appropriately revalue this CPT code to reflect an outpatient service we started with the original CY 2008 work RVU of 7.05 then, in accordance with the policy discussed in section II.B. of this proposed notice, we removed the value of the subsequent hospital care service and one-half discharge day management service, and added back the subsequent hospital care intra-service time to the immediate post-operative care service. As a result, we are proposing an alternative work RVU of 6.14 with refinements to the time for CPT code 42440 for CY 2012. A complete list of CMS time refinements can be found in Table 9.

(C) Urological Procedures

CPT Code	Short descriptor	AMA RUC Rec-ommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
53445	Insert uro/ves nck sphincter	15.39	Disagree	13.00
54410	Remove/replace penis prosth	15.18	Agree	15.18
54530	Removal of testis	8.46	Agree	8.46

For CY 2009, CPT code 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. The AMA RUC recommended that CPT code 53445 should be removed from the site-of-service anomaly screen and that the current work RVU of 15.21 should be maintained because, although the Medicare claims data indicated that this service is predominately furnished in the outpatient setting, survey respondents indicated this service is typically furnished in the facility setting. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 53445 used under the PFS was increased to 15.39 based on the redistribution of RVUs that resulted from our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation. Despite Medicare claims data showing that this service is typically furnished in the outpatient setting, the AMA RUC believes it is appropriate for CPT code 53445 to have inpatient visits because the specialty society that most commonly furnishes these procedures asserts that the typical patient spends at least one night in the hospital. The AMA RUC has requested that the specialty society conduct an additional survey to address more specifically whether an overnight stay is

typical for CPT code 53445 and 54410. The AMA RUC recommended that the current work RVU of 15.39 for CPT code 53445 be maintained.

We disagree with the AMA RUC-recommended work RVU of 15.39 for CPT code 53445 and believe a work RVU of 13.00 is more appropriate for this service. As stated previously in our discussion of 23-hour stay codes, as well as in the CY 2010 PFS final rule with comment period (74 FR 61777), even though a service may typically have a lengthy hospital outpatient recovery period, it should not reflect work that is typically associated with an inpatient service. Upon clinical review of this service and the time and visits associated with it, we believe that the survey 25th percentile work RVU of 13.00 appropriately accounts for the work required to furnish this service. Therefore, we are proposing a work RVU of 13.00 for CPT code 53445 for CY 2012.

(D) Epidural Lysis

CPT Code	Short descriptor	AMA RUC Recommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
62263	Epidural lysis mult sessions	6.54	Disagree	5.00

For CY 2009, CPT code 62263 (Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days,) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended maintaining the current (CY 2008) work RVU of 6.41 for this service and removing the inpatient subsequent hospital care visits to reflect the current outpatient place of service. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 62263 used under the PFS was increased to 6.54 based on the redistribution of RVUs that resulted from our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and recommended that the current work RVU of 6.54 for CPT code 62263 be maintained.

We disagree with the AMA RUC-recommended work RVU of 6.45 for CPT code 62263. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Upon clinical review, we believe that the survey median work RVU of 5.00 appropriately accounts for the removal of the inpatient visits as well as the increase in intra-service time and post-operative office visits in this service. Therefore, we are proposing a work RVU of 5.00 for CPT code 62263 for CY 2012.

(E) Intrathecal Epidural Catheters and Pumps

CPT Code	Short descriptor	AMA RUC Recommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
62350	Implant spinal canal cath	6.05	Agree	6.05
62355	Remove spinal canal catheter	4.35	Disagree	3.55
62360	Insert spine infusion device	4.33	Agree	4.33
62361	Implant spine infusion pump	5.65	Disagree	5.00
62362	Implant spine infusion pump	6.10	Disagree	5.60
62365	Remove spine infusion device	4.65	Disagree	3.93

For CY 2009, CPT code 62355 (Removal of previously implanted intrathecal or epidural catheter) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended a work RVU of 4.30, approximately midway between the survey median and 75th percentile. The AMA RUC recommended removing the inpatient building blocks to reflect the outpatient site-of-service, removing all but 1 of the post-procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 62355 used under the PFS was increased to 4.35 based on the redistribution of RVUs that resulted from the CMS policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 4.35 for CPT code 62355 be maintained.

We disagree with the AMA RUC-recommended work RVU of 4.35 for CPT code 62355. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We do not believe that the reduction from the CY 2008 work RVU of 6.60 to the CY 2009 work RVU of 4.30 adequately accounts for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. Upon clinical review, we believe that the survey median work RVU of 3.55 appropriately accounts for the removal of the inpatient visits and decreased

time for this service. Therefore, we are proposing a work RVU of 3.55 for CPT code 62355 for CY 2012.

For CY 2009, CPT code 62361 (Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended a work RVU of 5.60, approximately midway between the survey median and 75th percentile. The AMA RUC recommended removing the inpatient visits to reflect the outpatient site-of-service, removing all but 1 of the post-procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 62361 used under the PFS was increased to 5.65 based on the redistribution of RVUs that resulted from our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 5.65 for CPT code 62361 be maintained.

We disagree with the AMA RUC-recommended work RVU of 5.65 for CPT code 62361. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We do not believe that the reduction from the CY 2008 work RVU of 6.59 to the CY 2009 work RVU of 5.60 adequately accounts for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. Upon clinical review, we believe that the survey 25th percentile work RVU of 5.00 appropriately accounts for the removal of the inpatient visits and decreased time for this service. Therefore, we are proposing a work RVU of 5.00 for CPT code 62361 for CY 2012.

For CY 2009, CPT code 62362 (Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended a work RVU of 6.05, approximately midway between the survey median and 75th percentile. The AMA RUC recommended removing the inpatient visits to reflect the outpatient site-of-service, removing all but 1 of the post-procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. In CY 2010, while CMS adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 62362 used under the PFS was increased to 6.10 based on the redistribution of RVUs that resulted from our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 6.10 for CPT code 62362 be maintained.

We disagree with the AMA RUC-recommended work RVU of 6.10 for CPT code 62362. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We do not believe that the reduction from the CY 2008 work RVU of 8.58 to the CY 2009 work RVU of 6.05 adequately accounts for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. Upon clinical review, we believe that the survey median work RVU of 5.60 appropriately accounts for the removal of the inpatient visits and decreased time for this service. Therefore, we are proposing a work RVU of 5.60 for CPT code 62362 for CY 2012.

For CY 2009, CPT code 62365 (Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended a work RVU of 4.60, the survey median. The AMA RUC recommended removing the inpatient visits to reflect the outpatient site-of-service, removing all but 1 of the post-procedure office visits to reflect the shift in global period from 90 days to 10 days, and reducing the physician time associated with this service. In CY 2010, while CMS adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 62365 used under the PFS was increased to 4.65 based on the redistribution of RVUs that resulted from our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 4.65 for CPT code 62365 be maintained.

We disagree with the AMA RUC-recommended work RVU of 4.65 for CPT code 62365. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. We do not believe that the reduction from the CY 2008 work RVU of 6.57 to the CY 2009 work RVU of 4.60 adequately accounts for the removal of 3 subsequent hospital care visits and half a discharge management day, which together represent a work RVU of 5.40. Also, the time required to furnish this service dropped significantly, even after considering the global period change. We believe that this service is similar to that of CPT code 33241 (Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator) which has a work RVU of 3.29 but does not include a half day of discharge management service. Upon clinical review, we believe that a work RVU of 3.93, that is a work RVU of 3.29 plus a work RVU of 0.64 to account for the half day of discharge management service, appropriately accounts for the removal of the inpatient visits and decreased time for this service. Therefore, we are proposing a work RVU of 3.93 for CPT code 62365 for CY 2012.

(F) Neurostimulators

CPT Code	Short descriptor	AMA RUC Rec-ommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
63650	Implant neuroelectrodes	7.20	Disagree	7.15
63685	Insrt/redo spine n generator	6.05	Disagree	5.19

For CY 2009, CPT code 63650 (Percutaneous implantation of neurostimulator electrode array, epidural) or mechanical means (such as, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days, was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended the survey median work RVU of 7.15, and removing the inpatient subsequent hospital care visits to reflect the current outpatient place of service. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 63650 used under the PFS was increased to 7.20 based on the redistribution of RVUs that resulted from the our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 7.20 for CPT code 63650 be maintained.

We disagree with the AMA RUC-recommended work RVU of 7.20 for CPT code 63650. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Upon clinical review, we believe that the survey median work RVU of 7.15 appropriately accounts for the removal of the inpatient visits, as well as the physician time and post-operative office visit changes. Therefore, we are proposing a work RVU of 7.15 for CPT code 63650 for CY 2012.

For CY 2009, CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on reference services and specialty survey data, the AMA RUC recommended the survey median work RVU of 6.00, and removing the inpatient subsequent hospital care visits to reflect the current outpatient place of service. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 63685 used under the PFS was increased to 7.05 based on the redistribution of RVUs that resulted from the our policy to no longer recognize the CPT consultation codes (74 FR 61775). Upon re-review for CY 2012, the AMA RUC reaffirmed its previous recommendation and ultimately recommended that the current work RVU of 6.05 for CPT code 63685 be maintained.

We disagree with the AMA RUC-recommended work RVU of 6.05 for CPT code 63685. As stated previously, we believe the appropriate methodology for valuing site-of-service anomaly codes entails not just removing the inpatient visits, but also accounting for the removal of the inpatient visits in the work value of the CPT code. Upon clinical review, we believe that the survey 25th percentile work RVU of 5.19 appropriately accounts for the removal of the inpatient visits, as well as the physician time and post-operative office visit changes. Therefore, we are proposing a work RVU of 5.19 for CPT code 63685 for CY 2012.

(G) Repair of Eye Wound

CPT Code	Short descriptor	AMA RUC Rec'ommended work RVU	CMS Work RVU decision	CMS Proposed work RVU
65285	Repair of eye wound	16.00	Disagree	15.36

Data suggest that CPT code 65285 (Repair of laceration; cornea and/or sclera, perforating, with reposition or resection of uveal tissue) is a ''23-hour stay'' outpatient service. For these 23-hour stay services, the typical patient is commonly at the hospital for less than 24 hours, but often stays overnight at the hospital. As we discussed previously and in the Five-Year Review of Work (76 FR 32410), we believe that the values of the codes that fall into the 23-hour stay category should not reflect work that is typically associated with an inpatient service.

For CY 2009, CPT code 65285 was identified as potentially misvalued through the site-of-service anomaly screen and was reviewed by the AMA RUC. Based on specialty survey data indicating that this service typically requires an overnight stay, the AMA RUC recommended removing the CPT code from the site-of-service anomaly list and maintaining the current (CY 2008) work RVU of 14.43, as well as current physician times and visits. In CY 2010, while we adopted the AMA RUC-recommended work value on an interim final basis and referred the service back to the AMA RUC to be reexamined, the work RVU for CPT code 65285 used under the PFS was increased to 14.71 based on the redistribution of RVUs that resulted from the our policy to no longer recognize the CPT consultation codes (74 FR 61775).

The AMA RUC re-reviewed CPT code 65285 for CY 2012 and recommended removing the half day of subsequent hospital care service, but contrary to the 23-hour stay policy we finalized in the CY 2011 PFS final rule with comment period (75 FR 73226 through 73227), recommended maintaining the one full day of discharge management service. The AMA RUC also recommended an increase in intra-service time and post-procedure office visits. Ultimately, the AMA RUC recommended a work RVU of 16.00 for CPT code 65285 for CY 2012.

We disagree with the AMA RUC recommended value for CPT code 65285. As the most recently available Medicare claims data suggest these two site-of-service anomaly codes resemble 23-hour stay outpatient services, and since the AMA RUC's recommended value continues to include one full day of discharge management service, we applied the 23-hour stay policy described previously. That is, we reduced the one day of discharge management service to one-half day, and adjusted physician work RVUs and times accordingly. As a result, we are proposing an alternative work RVU of 15.36 with refinements to the time for CPT code 65285 for CY 2012.

A complete list of CMS time refinements can be found in Table 9.

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TABLE 9: PHYSICIAN TIME AND WORK VALUES FOR CY 2009 AND 2010 SITE-OF-SERVICE ANOMALY CODES ADDRESSED IN THIS CY 2012 PFS PROPOSED RULE

HCPCS Code	Short Descriptor	Source	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day- 99238	Subsequent Observation Care- 99224	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213
21025	Excision of bone, lower jaw	CY 2008	11.07	75	0	0	120	43	1	1	0	1	0	2	2	2
21025	Excision of bone, lower jaw	CY 2009	9.87	60	10	15	90	30	0	0	0	0	0	0	2	2
21025	Excision of bone, lower jaw	Current	10.03	60	10	15	90	30	0	0	0	0	0	0	2	2
21025	Excision of bone, lower jaw	RUC Rec	10.03	60	10	15	90	30	0	0	0	0	0	0	2	2
21025	**Excision of bone, lower jaw**	**CMS Rec**	**10.03**	**60**	**10**	**15**	**90**	**30**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**2**
23415	Release of shoulder ligament	CY 2008	10.09	24	0	25	62	23	0.5	0	0	1	0	0	3.5	0
23415	Release of shoulder ligament	CY 2009	9.07	40	15	15	60	20	0	0	0	0.5	0	0	2	2
23415	Release of shoulder ligament	Current	9.23	40	15	15	60	20	0	0	0	0.5	0	0	2	2
23415	Release of shoulder ligament	RUC Rec	9.23	40	15	15	60	20	0	0	0	0	0	0	0	0
23415	**Release of shoulder ligament**	**CMS Rec**	**9.23**	**40**	**15**	**15**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
25116	Remove wrist/forearm lesion	CY 2008	7.38	21	0	15	78	21	1.5	0	0	1	0	0	5	0
25116	Remove wrist/forearm lesion	CY 2009	7.38	40	10	15	60	20	0	0	0	0.5	0	0	1	3
25116	Remove wrist/forearm lesion	Current	7.56	40	10	15	60	20	0	0	0	0.5	0	0	1	3
25116	Remove wrist/forearm lesion	RUC Rec	7.56	40	10	15	60	20	0	0	0	0.5	0	0	1	3
25116	**Remove wrist/forearm lesion**	**CMS Rec**	**7.56**	**40**	**10**	**15**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**1**	**3**
28725	Fusion of foot bones	CY 2008	11.97	25	0	25	89	22	2.5	0	0	1	0	0	4	0
28725	Fusion of foot bones	CY 2009	11.97	25	0	25	89	22	2.5	0	0	1	0	0	4	0
28725	Fusion of foot bones	Current	12.18	45	10	15	90	20	1	0	0	1	0	0	2	3
28725	Fusion of foot bones	RUC Rec	12.18	33	10	15	90	20	0	0	0	1	1	0	2	3
28725	**Fusion of foot bones**	**CMS Rec**	**11.22**	**33**	**10**	**15**	**90**	**30**	**0**	**0**	**0**	**0.5**	**0**	**0**	**2**	**0**
28730	Fusion of foot bones	CY 2008	12.21	60	0	0	120	30	1	0	0	1	0	0	0	5
28730	Fusion of foot bones	CY 2009	12.21	60	0	0	120	30	1	0	0	1	0	0	0	5
28730	Fusion of foot bones	Current	12.42	45	10	15	100	20	1	0	0	1	0	0	2	3

HCPCS Code	Short Descriptor	Source	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day- 99238	Subsequent Observation Care- 99224	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213
28730	Fusion of foot bones	RUC Rec	12.42	33	10	15	100	20	0	0	0	1	1	0	2	3
28730	**Fusion of foot bones**	**CMS Rec**	**10.70**	**33**	**10**	**15**	**100**	**30**	**0**	**0**	**0**	**0.5**	**0**	**0**	**2**	**3**
42440	Excise submaxillary gland	CY 2008	7.05	22	0	25	71	19	0.5	0	0	1	0	0	1.5	0
42440	Excise submaxillary gland	CY 2009	7.05	30	10	15	60	20	0	0	0	0.5	0	0	1	1
42440	Excise submaxillary gland	Current	7.13	30	10	15	60	20	0	0	0	0.5	0	0	1	1
42440	Excise submaxillary gland	RUC Rec	7.13	30	10	15	60	20	0	0	0	0.5	0	0	1	1
42440	**Excise submaxillary gland**	**CMS Rec**	**6.14**	**30**	**10**	**15**	**60**	**25**	**0**	**0**	**0**	**0.5**	**0**	**0**	**1**	**1**
52341	Cysto w/ureter stricture tx	CY 2008	6.11	47.5	0	0	60	30	1	0	0	0	0	0	0	0
52341	Cysto w/ureter stricture tx	CY 2009	5.35	45	10	15	45	20	0	0	0	0	0	0	0	0
52341	Cysto w/ureter stricture tx	Current	5.35	45	10	15	45	20	0	0	0	0	0	0	0	0
52341	Cysto w/ureter stricture tx	RUC Rec	5.35	45	10	15	45	20	0	0	0	0	0	0	0	0
52341	**Cysto w/ureter stricture tx**	**CMS Rec**	**5.35**	**45**	**10**	**15**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52342	Cysto w/up stricture tx	CY 2008	6.61	60	0	0	65	30	1	0	0	0	0	0	0	0
52342	Cysto w/up stricture tx	CY 2009	5.85	40	10	10	60	20	0	0	0	0	0	0	0	0
52342	Cysto w/up stricture tx	Current	5.85	40	10	10	60	20	0	0	0	0	0	0	0	0
52342	Cysto w/up stricture tx	RUC Rec	5.85	40	10	10	60	20	0	0	0	0	0	0	0	0
52342	**Cysto w/up stricture tx**	**CMS Rec**	**5.85**	**40**	**10**	**10**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52343	Cysto w/renal stricture tx	CY 2008	7.31	60	0	0	90	30	1	0	0	0	0	0	0	0
52343	Cysto w/renal stricture tx	CY 2009	6.55	45	10	10	60	25	0	0	0	0	0	0	0	0
52343	Cysto w/renal stricture tx	Current	6.55	45	10	10	60	25	0	0	0	0	0	0	0	0
52343	Cysto w/renal stricture tx	RUC Rec	6.55	45	10	10	60	25	0	0	0	0	0	0	0	0
52343	**Cysto w/renal stricture tx**	**CMS Rec**	**6.55**	**45**	**10**	**10**	**60**	**25**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52344	Cysto/uretero, stricture tx	CY 2008	7.81	60	0	0	77.5	30	1	0	0	0	0	0	0	0
52344	Cysto/uretero, stricture tx	CY 2009	7.05	40	10	10	45	20	0	0	0	0	0	0	0	0
52344	Cysto/uretero, stricture tx	Current	7.05	40	10	10	45	20	0	0	0	0	0	0	0	0
52344	Cysto/uretero, stricture tx	RUC Rec	7.05	40	10	10	45	20	0	0	0	0	0	0	0	0
52344	**Cysto/uretero, stricture tx**	**CMS Rec**	**7.05**	**40**	**10**	**10**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

HCPCS Code	Short Descriptor	Source	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day- 99238	Subsequent Observation Care- 99224	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213
52345	Cysto/uretero w/up stricture	CY 2008	8.31	50	0	0	90	30	1	0	0	0	0	0	0	0
52345	Cysto/uretero w/up stricture	CY 2009	7.55	45	10	15	45	20	0	0	0	0	0	0	0	0
52345	Cysto/uretero w/up stricture	Current	7.55	45	10	15	45	20	0	0	0	0	0	0	0	0
52345	Cysto/uretero w/up stricture	RUC Rec	7.55	45	10	15	45	20	0	0	0	0	0	0	0	0
52345	**Cysto/uretero w/up stricture**	**CMS Rec**	**7.55**	**45**	**10**	**15**	**45**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52346	Cystouretero w/renal strict	CY 2008	9.34	45	0	0	120	30	1	0	0	0	0	0	0	0
52346	Cystouretero w/renal strict	CY 2009	8.58	40	10	10	60	20	0	0	0	0	0	0	0	0
52346	Cystouretero w/renal strict	Current	8.58	40	10	10	60	20	0	0	0	0	0	0	0	0
52346	Cystouretero w/renal strict	RUC Rec	8.58	40	10	10	60	20	0	0	0	0	0	0	0	0
52346	**Cystouretero w/renal strict**	**CMS Rec**	**8.58**	**40**	**10**	**10**	**60**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
52400	Cystouretero w/congen repr	CY 2008	10.06	90	0	0	60	30	1	0	0	1	0	0	0	1
52400	Cystouretero w/congen repr	CY 2009	8.66	72.5	10	15	40	25	0	0	0	0.5	0	0	1	0
52400	Cystouretero w/congen repr	Current	8.69	72.5	10	15	40	25	0	0	0	0.5	0	0	1	0
52400	Cystouretero w/congen repr	RUC Rec	8.69	72.5	10	15	40	25	0	0	0	0.5	0	0	1	0
52400	**Cystouretero w/congen repr**	**CMS Rec**	**8.69**	**72.5**	**10**	**15**	**40**	**25**	**0**	**0**	**0**	**0.5**	**0**	**0**	**1**	**0**
52500	Revision of bladder neck	CY 2008	9.39	40	0	0	45	35	1	0	0	1	0	0	0	3
52500	Revision of bladder neck	CY 2009	7.99	45	10	15	45	27.5	0	0	0	0.5	0	0	0	3
52500	Revision of bladder neck	Current	8.14	45	10	15	45	27.5	0	0	0	0.5	0	0	0	3
52500	Revision of bladder neck	RUC Rec	8.14	45	10	15	45	27.5	0	0	0	0.5	0	0	0	3
52500	**Revision of bladder neck**	**CMS Rec**	**8.14**	**45**	**10**	**15**	**45**	**27.5**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**3**
53445	Insert uro/ves nck sphincter	CY 2008	15.21	50	0	25	126	24	3	0	0	1	0	0	0	3
53445	Insert uro/ves nck sphincter	CY 2009	15.21	50	15	20	90	25	0	1	1	1	0	0	1	3
53445	Insert uro/ves nck sphincter	Current	15.39	50	15	20	90	25	0	1	1	1	0	0	1	3
53445	Insert uro/ves nck sphincter	RUC Rec	15.39	50	15	20	90	25	0	0	0	1	1	0	1	3
53445	**Insert uro/ves nck sphincter**	**CMS Rec**	**13.00**	**50**	**15**	**20**	**90**	**25**	**0**	**0**	**0**	**1**	**1**	**0**	**1**	**3**
54410	Remove/replace penis prosth	CY 2008	16.48	50	0	0	145	30	1	0	0	1	0	0	0	2
54410	Remove/replace penis prosth	CY 2009	15.00	40	10	15	120	30	0	0	0	1	0	0	1	3

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54410	Remove/replace penis prosth	Current	15.18	40	10	15	120	30	0	0	0	1	0	0	1	3
54410	Remove/replace penis prosth	RUC Rec	15.18	40	10	15	120	30	0	0	0	1	1	0	1	3
54410	**Remove/replace penis prosth**	**CMS Rec**	**15.18**	**40**	**10**	**15**	**120**	**30**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**3**
54530	Removal of testis	CY 2008	9.31	33	0	25	58	17	0.5	0	0	1	0	0	0	2.5
54530	Removal of testis	CY 2009	8.35	57.5	10	15	60	30	0	0	0	0.5	0	0	2	1
54530	Removal of testis	Current	8.46	57.5	10	15	60	30	0	0	0	0.5	0	0	2	1
54530	Removal of testis	RUC Rec	8.46	57.5	10	15	60	30	0	0	0	0.5	0	0	2	1
54530	**Removal of testis**	**CMS Rec**	**8.46**	**57.5**	**10**	**15**	**60**	**30**	**0**	**0**	**0**	**0.5**	**0**	**0**	**2**	**1**
62263	Epidural lysis mult sessions	CY 2008	6.41	40	0	0	30	20	2	0	0	1	0	0	2	0
62263	Epidural lysis mult sessions	CY 2009	6.41	33	10	5	45	20	0	0	0	0.5	0	0	1	2
62263	Epidural lysis mult sessions	Current	6.54	33	10	5	45	20	0	0	0	0.5	0	0	1	2
62263	Epidural lysis mult sessions	RUC Rec	6.54	33	10	5	45	20	0	0	0	0.5	0	0	1	2
62263	**Epidural lysis mult sessions**	**CMS Rec**	**5.00**	**33**	**10**	**5**	**45**	**40**	**0**	**0**	**0**	**0.5**	**0**	**0**	**1**	**2**
62350	Implant spinal canal cath	CY 2008	8.04	70	0	0	60	125	1	0	2	1	0	0	4	0
62350	Implant spinal canal cath	CY 2009	6.00	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62350	Implant spinal canal cath	Current	6.05	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62350	Implant spinal canal cath	RUC Rec	6.05	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62350	**Implant spinal canal cath**	**CMS Rec**	**6.05**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
62355	Remove spinal canal catheter	CY 2008	6.60	60	0	0	40	130	1	0	2	1	0	0	3	0
62355	Remove spinal canal catheter	CY 2009	4.30	33	10	5	30	20	0	0	0	0.5	0	0	0	1
62355	Remove spinal canal catheter	Current	4.35	33	10	5	30	20	0	0	0	0.5	0	0	0	1
62355	Remove spinal canal catheter	RUC Rec	4.35	33	10	5	30	20	0	0	0	0.5	0	0	0	1
62355	**Remove spinal canal catheter**	**CMS Rec**	**3.55**	**33**	**10**	**5**	**30**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
62360	Insert spine infusion device	CY 2008	3.68	60	0	0	55	123	0	0	2	1	0	0	4	0
62360	Insert spine infusion device	CY 2009	4.28	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62360	Insert spine infusion device	Current	4.33	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62360	Insert spine infusion device	RUC Rec	4.33	33	10	5	60	20	0	0	0	0.5	0	0	0	1

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62360	**Insert spine infusion device**	**CMS Rec**	**4.33**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
62361	Implant spine infusion pump	CY 2008	6.59	60	0	0	60	130	1	0	2	1	0	0	4	0
62361	Implant spine infusion pump	CY 2009	5.60	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62361	Implant spine infusion pump	Current	5.65	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62361	Implant spine infusion pump	RUC Rec	5.65	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62361	**Implant spine infusion pump**	**CMS Rec**	**5.00**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
62362	Implant spine infusion pump	CY 2008	8.58	75	0	0	90	150	0	0	3	1	0	0	4	0
62362	Implant spine infusion pump	CY 2009	6.05	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62362	Implant spine infusion pump	Current	6.10	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62362	Implant spine infusion pump	RUC Rec	6.10	33	10	5	60	20	0	0	0	0.5	0	0	0	1
62362	**Implant spine infusion pump**	**CMS Rec**	**5.60**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
62365	Remove spine infusion device	CY 2008	6.57	60	0	0	45	125	1	0	2	1	0	0	3	0
62365	Remove spine infusion device	CY 2009	4.60	33	10	5	45	20	0	0	0	0.5	0	0	0	1
62365	Remove spine infusion device	Current	4.65	33	10	5	45	20	0	0	0	0.5	0	0	0	1
62365	Remove spine infusion device	RUC Rec	4.65	33	10	5	45	20	0	0	0	0.5	0	0	0	1
62365	**Remove spine infusion device**	**CMS Rec**	**3.93**	**33**	**10**	**5**	**45**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
63650	Implant neuroelectrodes	CY 2008	7.57	26	5	25	74	19	2.5	0	0	1	0	0	0	2
63650	Implant neuroelectrodes	CY 2009	7.15	33	10	5	60	20	0	0	0	0.5	0	0	0	1
63650	Implant neuroelectrodes	Current	7.20	33	10	5	60	20	0	0	0	0.5	0	0	0	1
63650	Implant neuroelectrodes	RUC Rec	7.20	33	10	5	60	20	0	0	0	0.5	0	0	0	1
63650	**Implant neuroelectrodes**	**CMS Rec**	**7.15**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
63685	Insrt/redo spine n generator	CY 2008	7.87	28	0	25	62	18	2.5	0	0	1	0	0	0	2
63685	Insrt/redo spine n generator	CY 2009	6.00	33	10	5	60	20	0	0	0	0.5	0	0	0	1
63685	Insrt/redo spine n generator	Current	6.05	33	10	5	60	20	0	0	0	0.5	0	0	0	1
63685	Insrt/redo spine n generator	RUC Rec	6.05	33	10	5	60	20	0	0	0	0.5	0	0	0	1
63685	**Insrt/redo spine n generator**	**CMS Rec**	**5.19**	**33**	**10**	**5**	**60**	**20**	**0**	**0**	**0**	**0.5**	**0**	**0**	**0**	**1**
64708	Revise arm/leg nerve	CY 2008	6.22	21	0	25	76	18	0.5	0	0	1	0	0	2.5	0

HCPCS Code	Short Descriptor	Source	Work RVU	Pre-Service Evaluation Minutes	Pre-Service Positioning Minutes	Pre-Service Dress, Scrub, Wait Minutes	Intra-Service Minutes	Same Day Post-Service Minutes	Subsequent Hospital Care- 99231	Subsequent Hospital Care- 99232	Subsequent Hospital Care- 99233	Hospital Discharge Day- 99238	Subsequent Observation Care- 99224	Office/Outpatient Visit, Est- 99211	Office/Outpatient Visit, Est- 99212	Office/Outpatient Visit, Est- 99213
64708	Revise arm/leg nerve	CY 2009	6.22	35	10	10	60	15	0	0	0	0.5	0	0	3	1
64708	Revise arm/leg nerve	Current	6.36	35	10	10	60	15	0	0	0	0.5	0	0	3	1
64708	Revise arm/leg nerve	RUC Rec	6.36	35	10	10	60	15	0	0	0	0.5	0	0	3	1
64708	**Revise arm/leg nerve**	**CMS Rec**	**6.36**	**35**	**10**	**10**	**60**	**15**	**0**	**0**	**0**	**0.5**	**0**	**0**	**3**	**1**
64831	Repair of digit nerve	CY 2008	10.23	25	0	25	74	21	1	0	0	1	0	0	0	2.5
64831	Repair of digit nerve	CY 2009	9.00	40	10	15	60	15	0	0	0	0.5	0	0	2	2
64831	Repair of digit nerve	Current	9.16	40	10	15	60	15	0	0	0	0.5	0	0	2	2
64831	Repair of digit nerve	RUC Rec	9.16	40	10	15	60	15	0	0	0	0.5	0	0	2	2
64831	**Repair of digit nerve**	**CMS Rec**	**9.16**	**40**	**10**	**15**	**60**	**15**	**0**	**0**	**0**	**0.5**	**0**	**0**	**2**	**2**
65285	Repair of eye wound	CY 2008	14.43	37	0	15	79	32	0.5	0	0	1	0	0	0	5.5
65285	Repair of eye wound	CY 2009	14.43	37	0	15	79	32	0.5	0	0	1	0	0	0	5.5
65285	Repair of eye wound	Current	14.71	37	0	15	79	32	0.5	0	0	1	0	0	0	5.5
65285	Repair of eye wound	RUC Rec	16.00	30	10	20	90	30	0	0	0	1	0	0	1	6
65285	**Repair of eye wound**	**CMS Rec**	**15.36**	**30**	**10**	**20**	**90**	**30**	**0**	**0**	**0**	**0.5**	**0**	**0**	**1**	**6**

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b. Payment for Bone Density Tests

Section 1848(b)(6) of the Act (as amended by section 3111(a) of the Affordable Care Act) changed the payment calculation for dual-energy x-ray absorptiometry (DXA) services described by two specified DXA CPT codes for CYs 2010 and 2011. This provision required payment for these services at 70 percent of the product of the CY 2006 RVUs for these DXA codes, the CY 2006 CF, and the geographic adjustment for the relevant payment year.

Effective January 1, 2007, the CPT codes for DXA services were revised. The former DXA CPT codes 76075 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites;

axial skeleton (eg, hips, pelvis, spine)); 76076 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; appendicular skeleton (peripheral) (for example, radius, wrist, heel)); and 76077 (Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; vertebral fracture assessment) were deleted and replaced with new CPT codes 77080, 77081, and 77082 that have the same respective code descriptors as the predecessor codes. Section 1848(b) of the Act, as amended, specifies that the revised payment applies to two of the predecessor codes (CPT codes 76075 and 76077) and ''any succeeding codes,'' which are, in this case, CPT codes 77080 and 77082.

As mentioned previously, section 1848(b) of the Act revised the payment for CPT codes 77080 and 77082 during CY 2010 and CY 2011. We provided for payment in CYs 2010 and 2011 under the PFS for CPT codes 77080 and 77082 at the specified rates (70 percent of the product of the CY 2006 RVUs for these DXA codes, the CY 2006 conversion factor (CF), and the geographic adjustment for the relevant payment year). Because the statute specifies a payment calculation for these services for CYs 2010 and 2011 as described previously, for those years we implemented the payment provision by imputing RVUs for these services that would provide the specified payment amount for these services when multiplied by the current year's conversion factor.

For CY 2012, the payment rate for CPT codes 77080 and 77082 will be based upon resource-based, rather than imputed, RVUs, and the current year's conversion factor. The CY 2012 work, PE, and malpractice RVUs for these codes are shown in Table 10, as well as in Addendum B of this proposed rule.

TABLE 10—CY 2012 RVUS FOR DXA CPT CODES 77080 AND 77082

CPT Code	Modifier	Physician work RVU	Fully implemented non-facility PE RVU	Transitional non-facility PE RVU	Fully implemented facility PE RVU	Transitional facility PE RVU	Malpractice RVU
77080		0.20	1.26	1.44	NA	NA	0.02
77080	TC	0.00	1.18	1.36	NA	NA	0.01
77080	26	0.20	0.08	0.08	0.08	0.08	0.01
77082		0.17	0.63	0.65	NA	NA	0.02
77082	TC	0.00	0.56	0.58	NA	NA	0.01
77082	26	0.17	0.07	0.07	0.07	0.07	0.01

In addition to temporarily changing the payment rate for the two DXA CPT codes, section 3111(b) of the Affordable Care Act also authorizes the Secretary to enter into agreement with the Institute of Medicine of the National Academies to conduct a study on the ramifications of Medicare payment reductions for dual-energy x-ray absorptiometry (as described in section 1848(b)(6) of the Act) during years 2007, 2008, and 2009 on beneficiary access to bone mass density tests. This study has not yet been conducted. In the absence of this study, we request that the AMA RUC review CPT codes 77080 and 77082 during CY 2012.

C. Expanding the Multiple Procedure Payment Reduction (MPPR) Policy

1. 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 the same physician on the same day, largely based on the presence of efficiencies in the practice expense (PE) and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with the 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, under the CY 2006 PFS, the MPPR policy was extended to the technical component (TC) of certain diagnostic imaging procedures performed on contiguous areas of the body in a single session (70 FR 70261). The reduction recognizes that, for the second and subsequent imaging procedures, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent procedures and, because equipment time and indirect costs are allocated based on clinical labor time, those would also be reduced 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. When we adopted the policy in CY 2007, we stated that we believed efficiencies were most likely to occur when imaging procedures are performed on contiguous body areas because the patient and equipment have already been prepared for the second and subsequent procedures, potentially yielding resource savings in areas such as clerical time, technical preparation, and supplies (70 FR 45850). The MPPR policy originally applied only to procedures furnished in a single session involving contiguous body areas within a family of codes, not across families. Additionally, while the MPPR policy applies to TC-only services and to the TC of global services, it does not apply to professional component (PC) services.

Under the current imaging MPPR policy, full payment is made for the TC of the highest paid procedure, and payment is reduced by 50 percent of the TC for each additional procedure when an MPPR scenario applies. 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

budget neutrality provision. Effective July 1, 2010, section 3135(b) of the Affordable Care Act amended the statute to increase 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, and exempted the reduced expenditures attributable to this further change from the PFS budget neutrality provision.

In the July 2009 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 (as added by section 3134(a) of the Affordable Care 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 services furnished to the same patient in the same session, regardless of the imaging modality, and is not limited to contiguous body areas.

We note that section 1848(c)(2)(B)(v)(VI) of the Act (as added by section 3135(b) of the Affordable Care Act) specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS budget neutrality adjustment. That is, the reduced payments for code combinations within a family of codes (contiguous body areas) are excluded from budget neutrality. However, this exclusion only applies to reduced expenditures attributable to the increase in the MPPR percentage from 25 to 50 percent, and not to reduced expenditures attributable to our policy change regarding additional code combinations across code families (non-contiguous body areas) that are subject to budget neutrality under the PFS.

The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 3134(a) of the Affordable Care Act, effective 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. Contractor-priced codes, bundled codes, and add-on codes are excluded because an MPPR would not be applicable for ''always therapy'' services furnished in combination with these codes. The complete list of codes subject to the MPPR policy for therapy services is included in Addendum H.

In the CY 2011 proposed rule (75 FR 44075), we proposed to apply 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. 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 (Pub. L. 111–286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services furnished in office settings. The payment reduction percentage remains at 25 percent for services furnished in institutional settings. Section 4 of the Physician Payment and Therapy Relief Act of 2010 exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS budget neutrality provision. Under our current policy as amended by the Physician Payment and Therapy Relief Act, 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.

The MPPR policy applies to multiple units of the same therapy service, as well as to multiple different 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 paid under the PFS that are furnished in the office setting, as well as to institutional services paid at the PFS rates that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid under Medicare Part B for outpatient therapy services.

2. CY 2012 Proposed Expansion of the MPPR Policy to the Professional Component of Advanced Imaging Services

Over the past 3 years, as part of the potentially misvalued service initiative, the AMA RUC has examined several services that are billed together at least 90 percent of the time as part of the potentially misvalued service initiative. In several cases, the AMA RUC recommended work values for new codes that describe the combined services, and those recommended values reflected the expected efficiencies. For example, for CY 2011, the AMA RUC valued the work for a series of new codes that describe CT of the abdomen and pelvis, specifically CPT codes:

- 74176 (Computed tomography, abdomen and pelvis; without contrast material).
- 74177 (Computed tomography, abdomen and pelvis; with contrast material).
- 74178 (Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by with contrast material(s) and further sections in one or both body regions).

We accepted the AMA RUC-recommended work values for these codes in the CY 2011 PFS final rule with comment period (75 FR 73229). The AMA RUC-recommended work values reflected an expected efficiency for the typical combined service that paralleled the reductions that would typically result from a MPPR adjustment. For example, in support of the recommended work value of 1.74 RVUs for 74176, the AMA RUC explained that the full value of 74150 (Computed tomography, abdomen; without contrast material) (Work RVU = 1.19) plus half the value of 72192 (Computed tomography, pelvis; without contrast material) (½ Work RVU = 0.55) equals 1.74 work RVUs. The AMA RUC stated that its recommended valuation was appropriate even though the combined current work RVUs for 74150 and 72192 would result in a total work RVU of 2.28. Furthermore, the AMA RUC validated its estimation of work efficiency for the combined service by comparing the code favorably with the work value associated with 74182 (Magnetic resonance, for example, proton imaging, abdomen; with contrast material(s)) (Work RVU = 1.73), which has a similar intra-service time, 20 minutes. Thus, we believe our current and proposed MPPR formulations are consistent with the AMA RUC's work to review code pairs for unaccounted-for efficiencies and to appropriately value comprehensive codes for a bundle of component services.

We continue to believe that there may be additional imaging and other diagnostic services for which there are efficiencies in work when furnished together, resulting in potentially excessive payment for these services under current policy.

As noted, Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures and nuclear medicine diagnostic procedures furnished to the same patient by the same physician on the same day. In continuing to apply the provisions of section 3134(a) of the Affordable Care Act, for CY 2012 we are proposing to expand 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 applies (see Addendum F). Thus, the MPPR would apply to the PC and the TC of the codes. Specifically, we propose to expand the 50 percent payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging services furnished in the same session. Full payment would be made for the PC and TC of the highest paid procedure, and payment would be reduced by 50 percent for the PC and TC for each additional procedure furnished to the same patient in the same session. This proposal is 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 proposal 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 3134(a) of the Affordable Care Act. The proposal is also consistent both with our longstanding policy on surgical and nuclear medicine diagnostic procedures, which apply a 50 percent reduction to second and subsequent procedures. Furthermore, it is responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

Finally, as noted, the proposal is consistent with the RUC's recent methodology and rationale in valuing the work for a combined CT of the pelvis (CPT codes 72192, 72193 and 72194), and abdomen (CPT codes 74150, 74160 and 74170) where the RUC assumed the work efficiency for the second service was 50 percent. Savings resulting from this proposal would be redistributed to other PFS services as required by the general statutory PFS budget neutrality provision.

3. Further Expansion of the MPPR Under Consideration for Future Years

Currently, the MPPR focuses only on a select number of codes. We will be aggressively looking for efficiencies in other sets of codes during the following years and will consider implementing more expansive reduction policies in CY 2013 and beyond. We invite public comment on the following MPPR policies which are under consideration. 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 performed in the same session. Such an approach could define imaging consistent with our existing definition of imaging for purposes of the statutory cap on 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. 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 budget neutrality 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.

This 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. 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 budget neutrality 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.

The approach would be based on the expected efficiencies due to duplication of clinical labor activities, supplies, and equipment time. The approach would apply to approximately 700 HCPCS codes, including the approximately 560 HCPCS codes subject to the OPPS cap. The savings would be redistributed to other PFS services as required by the statutory PFS budget neutrality provision.

D. Malpractice RVUs

1. Overview of the Methodology for Calculation of 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 amended section 1848(c) of the Act which 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, malpractice RVUs for new and revised codes effective before the next Five-Year Review (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 (75 FR 73208). 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 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 codes reviewed in this proposed rule the source code for each code is the code itself. Therefore, we calculated the revised malpractice RVU for these codes by scaling the current malpractice RVU by the percent difference in work RVU between the current (CY 2011) work RVU and the work RVU proposed in section II.B. of this proposed rule. Typically, the assigned malpractice RVUs for new/revised codes effective between updates remain in place until the next Five-Year Review of Malpractice, which is expected to occur for CY 2015. We anticipate soliciting public comments in the CY 2013 PFS proposed rule on matters relating to the CY 2015 Five-Year Review of Malpractice.

2. Proposed Revisions to Malpractice RVUs for Certain Cardiothoracic Surgery Services

In addition to the scaling of malpractice RVUs to account for the proportionate difference between current and proposed work RVUs (proposed work RVU changes are discussed previously in section II.B.of this proposed rule) there are 19 cardiothoracic surgery codes for which we propose to scale the malpractice RVUs to account for the proportionate difference between the current and proposed revised specialty risk factor. These codes and their short descriptors are listed below in Table 11. As discussed in the CY 2010 PFS proposed rule (74 FR 33539), we assign malpractice RVUs to each service based upon a weighted average of the malpractice risk factors of all specialties that furnish the service. For the CY 2010 review of malpractice RVUs, we used CY 2008 Medicare claims data on allowed services to establish the frequency of a service by specialty. For a number of cardiothoracic surgery CPT codes representing major open heart procedures performed primarily on neonates and infants, CY 2008 Medicare claims data showed zero allowed services. Therefore, our contractor set the number of services to 1, and assigned a risk factor according to the average risk factor for all services that do not explicitly have a separate technical or professional component (average risk factor = 1.95). In the CY 2010 PFS final rule with comment period, we published interim final malpractice RVUs for these codes calculated using the average physician risk factor, and finalized them in the CY 2011 PFS final rule with comment period.

However, since publication of the CY 2010 PFS final rule with comment period, stakeholders have expressed concern that the average risk factor is not appropriate for these services, and that a cardiac surgery risk factor would be more appropriate (cardiac surgery risk factor = 6.93). While these CPT codes continue to have little to no Medicare claims data, upon clinical review we agree that these CPT codes represent cardiac surgery services and that the malpractice RVUs should be calculated using the cardiac surgery risk factor. Accordingly, we propose to scale the malpractice RVUs for these CPT codes to reflect the proportionate difference between the average risk factor and the cardiac surgery risk factor. To scale the malpractice RVU we used the following formula: (cardiac surgery risk factor/average risk factor) * CY 2011 malpractice RVU = Proposed CY 2012 malpractice RVU. For example, CPT code 33471 (Valvotomy, pulmonary valve, closed heart; via pulmonary artery) has a CY 2011 malpractice RVU of 1.62 which was calculated using the average risk factor of 1.95. To scale this malpractice RVU to reflect the cardiac surgery risk factor of 6.93 we used the following calculation: (6.93 RF/1.95 RF)*1.62 MP RVU = 5.76 MP RVU.

CPT code 33692 (Complete repair tetralogy of Fallot without pulmonary atresia;) has a CY 2011 work RVU of 31.54 and a malpractice RVU of 2.23. However, in the Fourth Five-Year Review of Work (76 FR 32410) we have

proposed an interim final work RVU of 36.15 and adjusted the malpractice RVU to 2.56 for this service. Therefore, the starting value for calculating the proposed revised malpractice RVU based on the cardiac surgery risk factor is the Five-Year Review malpractice RVU instead of the CY 2011 malpractice RVU. Similar to the example shown previously, the formula for this adjustment is as follows: (cardiac surgery risk factor/average risk factor) * Five-Year Review malpractice RVU = Proposed CY 2012 malpractice RVU.

Table 11 shows the proposed CY 2012 malpractice RVUs for these cardiothoracic surgery codes.

We also propose to scale the malpractice RVU to reflect a change in risk factor for CPT code 32442 (Removal of lung, total pneumonectomy; with resection of segment of trachea followed by broncho-tracheal anastomosis (sleeve pneumonectomy)). In the CY 2010 review of malpractice RVUs we assigned CPT code 32442 the pulmonary disease risk factor (2.09) and published the interim final malpractice RVU calculated from this risk factor in the CY 2010 PFS final rule with comment period. This value was finalized in the CY 2011 PFS final rule with comment period.

Since finalizing this value, stakeholders have suggested that a blended risk factor of thoracic surgery (6.49) and general surgery (5.91) would be more appropriate for this service. As described in the CY 2010 PFS final rule with comment period (74 FR 61760), we do not use a blended risk factor for services with Medicare utilization under 100; instead, we use the malpractice risk factor of the specialty that performs the given service the most (the dominant specialty). As CPT code 32442 has Medicare utilization well below the 100 occurrences threshold, and current Medicare claims data show that the dominant specialty for CPT code 32442 is thoracic surgery, we believe that the thoracic surgery risk factor is the appropriate risk factor for this service at this time. Applying the formula described previously to adjust the malpractice RVU to reflect the thoracic surgery risk factor rather than the pulmonary disease risk factor results in a malpractice RVU of 13.21 for CPT code 32442. Therefore, we propose a malpractice RVU of 13.21 for CPT code 32442 for CY 2012. Table 11 shows the proposed CY 2012 malpractice RVUs for the cardiothoracic surgery codes described in this section. All malpractice RVUs are listed in Addendum B of this proposed rule, including those that are proposed to be revised and those for which there is no proposed change for CY 2012.

TABLE 11—CY 2012 PROPOSED MALPRACTICE (MP) RVUS FOR SELECTED CARDIOTHORACIC SURGERY SERVICES

CPT Code	Short descriptor	CY 2012 proposed specialty risk factor	CY 2011 MP RVU	Proposed CY 2012 MP RVU
33471	Valvotomy pulmonary valve	Cardiac Surgery: 6.93	1.62	5.76
33472	Revision of pulmonary valve	Cardiac Surgery: 6.93	1.63	5.80
33676	Close mult vsd w/resection	Cardiac Surgery: 6.93	2.63	9.36
33677	Cl mult vsd w/rem pul band	Cardiac Surgery: 6.93	2.74	9.75
33692	Repair of heart defects	Cardiac Surgery: 6.93	*2.56	9.11
33762	Major vessel shunt	Cardiac Surgery: 6.93	1.61	5.73
33768	Cavopulmonary shunting	Cardiac Surgery: 6.93	0.56	1.99
33771	Repair great vessels defect	Cardiac Surgery: 6.93	2.90	10.32
33775	Repair great vessels defect	Cardiac Surgery: 6.93	2.33	8.29
33776	Repair great vessels defect	Cardiac Surgery: 6.93	2.45	8.72
33777	Repair great vessels defect	Cardiac Surgery: 6.93	2.42	8.61
33778	Repair great vessels defect	Cardiac Surgery: 6.93	3.05	10.85
33779	Repair great vessels defect	Cardiac Surgery: 6.93	3.09	10.99
33780	Repair great vessels defect	Cardiac Surgery: 6.93	3.13	11.14
33781	Repair great vessels defect	Cardiac Surgery: 6.93	3.09	10.99
33786	Repair arterial trunk	Cardiac Surgery: 6.93	2.98	10.60
33788	Revision of pulmonary artery	Cardiac Surgery: 6.93	1.93	6.87
33822	Revise major vessel	Cardiac Surgery: 6.93	1.25	4.45
32442	Sleeve pneumonectomy	Thoracic Surgery: 6.49	4.25	13.21

*The malpractice RVU listed for CPT code 33692 is the Five-Year Review of Work-adjusted malpractice RVU, not the CY 2011 malpractice RVU. Please see above for additional detail.

E. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, physician work, practice expense (PE), and malpractice). While requiring that the PE and malpractice GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the physician 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 2009 until it was extended through December 31, 2010 by section 3102(a) of the Affordable Care Act. Because the work GPCI floor was set to expire at the end of 2010, the GPCIs published in Addendum E of the CY 2011 PFS final rule with comment period did not reflect the 1.0 physician work floor. However, section 1848(e)(1)(E) of the Act was amended on December 15, 2010, by section 103 of the Medicare and Medicaid Extenders Act (MMEA) of 2010 (Pub. L. 111–309) to extend the 1.0 work GPCI floor through December 31, 2011. Appropriate changes to the CY 2011 GPCIs were made to reflect the 1.0

physician work floor required by section 103 of the MMEA. Since the work GPCI floor provided in section 1848(e)(1)(E) of the Act is set to expire prior to the implementation of the CY 2012 PFS, the CY 2012 physician work GPCIs, and summarized geographic adjustment factors (GAFs), presented in this proposed rule do not reflect the 1.0 work GPCI floor. As required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier States will be applicable in CY 2012. Moreover, the limited recognition of cost differences in employee compensation and office rent for the PE GPCIs, and the related hold harmless provision, required under section 1848(e)(1)(H) of the Act was only applicable for CY 2010 and CY 2011 (75 FR 73253) and, therefore, is no longer effective beginning in CY 2012.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs not less often than every 3 years. This section also specifies that if more than 1 year has elapsed since the last GPCI revision, we must phase in the adjustment over 2 years, applying only one-half of any adjustment in the first year.

As noted in the CY 2011 PFS final rule with comment period (75 FR 73252 through 73262), for the sixth GPCI update, we updated the data used to compute all three GPCI components. Specifically, we utilized the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) to calculate the physician work GPCIs (75 FR 73252). In addition, we used the 2006 through 2008 BLS OES data to calculate the employee compensation sub-component of practice expense (75 FR 73255). Consistent with previous updates, we used the 2-bedroom residential apartment rent data from HUD (2010) at the 50th percentile as a proxy for the relative cost differences in physician office rents (75 FR 73256). Lastly, we calculated the malpractice GPCIs using malpractice premium data from 2006 through 2007 (75 FR 73256).

Since more than 1 year had elapsed since the fifth GPCI update, the sixth GPCI update changes are being phased in over a 2-year period as required by law. The current CY 2011 GPCIs reflect the first year of the transition. The proposed CY 2012 GPCIs reflect the full implementation.

The Affordable Care Act requires that we analyze the current methodology and data sources used to calculate the PE GPCI component. Specifically, section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the Affordable Care Act) requires the Secretary to ''analyze current methods of establishing practice expense adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the cost of operating a medical practice in different fee schedule areas.'' Section 1848(e)(1)(H)(iv) of the Act also requires that such analysis shall include an evaluation of the following:

- The feasibility of using actual data or reliable survey data developed by medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.
- The office expense portion of the practice expense geographic adjustment; including the extent to which types of office expenses are determined in local markets instead of national markets.
- The weights assigned to each area of the categories within the practice expense geographic adjustment.

In addition, the weights for different categories of practice expense in the GPCIs have historically matched the weights developed by the CMS Office of the Actuary (OACT) for use in the Medicare Economic Index (MEI), the measure of inflation used as part of the basis for the annual update to the physician fee schedule payment rates. In response to comments received on the CY 2011 Physician Fee Schedule proposed rule, however, we delayed moving to the new MEI weights developed by OACT for CY 2011 pending further analysis.

Lastly, we asked the Institute of Medicine (IOM) to evaluate the accuracy of the geographic adjustment factors used for Medicare physician payment. IOM will prepare three reports for the Congress and the Secretary of the Department of Health and Human Services. The first report (Phase I) was released on June 1, 2011, and includes an evaluation of the accuracy of geographic adjustment factors for the hospital wage index and the GPCIs, and the methodology and data used to calculate them. In addition, IOM is expected to release a supplemental GPCI report in the summer of 2011. The third report, expected in spring 2012, will evaluate the effects of the adjustment factors on the distribution of the health care workforce, quality of care, population health, and the ability to provide efficient, high value care. Given the timing of the release of IOM's first report and the fact that we do not yet have the second supplemental report on the GPCIs, we are unable to address the full scope of the IOM recommendations in this proposed rule. The report can be accessed on the IOM's Web site at *http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.* Additionally, we have included a summary of GPCI-specific recommendations in section 4 below.

2. Proposed GPCI Revisions for CY 2012

The revised GPCI values we are proposing were developed by Acumen, LLC (Acumen) under contract to us. As mentioned previously, there are three GPCI components (physician work, PE, and malpractice), and all GPCIs are developed through comparison to a national average for each component. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value, as described more fully later in this section. As discussed in more detail later in this section, we are proposing to revise the PE GPCIs for CY 2012, as well as the cost share weights which correspond to all three GPCIs.

a. Physician Work GPCIs

The physician work GPCIs are designed to capture the relative cost of physician labor by Medicare PFS locality. Previously, the physician 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. Including physicians' wages in the physician work GPCIs would, in effect, have made the indices dependent upon Medicare payments. As required by law, the physician work GPCI reflects one-quarter of the relative wage differences for each locality compared to the national average.

The physician 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 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) data as a replacement for the 2000 Census data. We are not proposing to revise the physician work GPCI data source for CY 2012. However, we note that the work GPCIs will be revised to account for the expiration of the statutory work floor. The 1.5 work floor for Alaska is permanent and will be applicable in CY 2012. In addition, we are proposing to revise the physician work cost share weight from 52.466 to 48.266 in line with the 2011 MEI weights, which are

based on 2006 data (referred to hereinafter as the 2006-based MEI).

b. Practice Expense GPCIs

(1) Affordable Care Act Analysis and Revisions for PE GPCIs

(A) General Analysis for the CY 2012 PE GPCIs

As previously mentioned, section 1848(e)(1)(H)(iv) of the Act (as added by section 3102(b) of the Affordable Care Act) requires the Secretary to ''analyze current methods of practice expense adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the cost of operating a medical practice in different fee schedule areas.''

Moreover, section 1848(e)(1)(H)(v) of the Act requires the Secretary to make appropriate adjustments to the PE GPCIs as a result of the required analysis no later than by January 1, 2012. We are proposing to make four revisions to the PE data sources and cost share weights discussed herein effective January 1, 2012. Specifically, we are proposing to: (1) Revise the occupations used to calculate the employee wage component of PE using BLS wage data specific to the office of physicians' industry; (2) utilize two bedroom rental data from the 2006–2008 American Community Survey as the proxy for physician office rent; (3) create a purchased service index that accounts for regional variation in labor input costs for contracted services from industries comprising the ''all other services'' category within the MEI office expense and the stand alone ''other professional expenses'' category of the MEI and; (4) use the 2006-based MEI (most recent MEI weights finalized in the CY 2011 final rule with comment period) to determine the GPCI cost share weights. These proposals are based on analyses we conducted to address commenter concerns in the CY 2011 final rule with comment period. The main comments were related to: (1) The occupational groups used to calculate the employee wage component of PE, and (2) concerns by commenters stating that regional variation in purchased services such as legal and accounting are not sufficiently included in the employee wage index.

We began analyzing the current methods and data sources used in the establishment of the PE GPCIs during the CY 2011 rulemaking process (75 FR 40084). With respect to our CY 2011 analysis, we began with a review of the Government Accountability Office's (GAO) March 2005 Report entitled, ''Medicare Physician Fees: Geographic Adjustment Indices Are Valid in Design, but Data and Methods Need Refinement'' (GAO–05–119). While we have raised concerns in the past about some of the GAO's GPCI recommendations, we noted that with respect to the PE GPCIs, the GAO did not indicate any significant issues with the methods underlying the PE GPCIs. Rather, the report focused on some of the data sources used in the method. For example, the GAO stated that the wage data used for the PE GPCIs are not current. Similarly, commenters on previous PE GPCI updates predominantly focused on either the data sources used in the method or raised issues such as incentivizing the provision of care in different geographic areas. However, the latter issue (incentivizing the provision of care) is outside the scope of the statutory requirement that the PE GPCIs reflect the relative costs of the mix of goods and services comprising practice expenses in the different fee schedule areas relative to the national average.

To further analyze the PE office expense in accordance with section 1848(e)(1)(H)(iv) of the Act, we examined the following issues: the appropriateness of expanding the number of occupations included in the employee wage index; the appropriateness of replacing rental data from the Department of Housing and Urban Development (HUD) with data from the 2006–2008 American Community Survey (ACS) two bedroom rental data as a proxy for the office rent subcomponent of PE; and the appropriateness of adjusting the ''all other services'' and ''other professional expenses'' MEI categories for geographic variation in labor-related costs. We also examined available ACS occupational group data for potential use in determining geographic variation in the employee wage component of PE.

An additional component of the analysis under section 1848(e)(1)(H)(iv) of the Act is to evaluate the weights assigned to each of the categories within the practice expense geographic adjustment. As discussed in the CY 2011 final rule with comment period (75 FR 73256), in response to concerns raised by commenters and to allow us time to conduct additional analysis, we did not revise the GPCI cost share weights to reflect the weights used in the revised and rebased 2006 MEI that we adopted beginning in CY 2011. In response to those commenters, whom raised many points regarding the appropriateness of assigning labor-related costs in the medical equipment and supplies and miscellaneous component which do not reflect locality cost differentials, we agreed to address the GPCI cost share weights again in the CY 2012 PFS proposal. These issues are discussed in greater detail in the section of this rule that discusses our determination of the cost share weights.

We also stated in the CY 2011 final rule with comment period that we would review the findings of the Secretary's Medicare Geographic Payment Summit and the MEI technical advisory panel during future rulemaking (75 FR 73256). The Secretary convened the National Summit on Health Care Quality and Value on October 4, 2010. This Summit was attended by a number of policy experts that engaged in detailed discussions regarding geographic adjustment factors and geographic variation in payment and the promotion of high quality care. This National Summit was useful to informing us on issues which we are studying further through three Institute of Medicine studies (including the recently released first of three reports on Geographic Adjustment Factors and a separate report on Geographic Variation in Health Care Spending and the Promotion of High Value Care). In accordance with Section 3102(b) of the Affordable Care Act, we are also continuing to consider these issues in the course of notice and comment rulemaking for the CY 2012 PFS, which includes revisions to the GPCI, and through preparation of a report to the Congress that we will be submitting later this year in accordance with section 3137(b) of the Affordable Care Act on a plan for reforming the hospital wage index. In addition, the Agency is currently working through the various administrative requirements to formally organize the MEI technical advisory panel. We expect that this panel will be convened in the near future. We look forward to examining the recommendations of this panel once it has issued its report.

(B) Analysis of ACS Rental Data

In the CY 2011 final rule with comment period, we finalized our policy to use the 2010 apartment rental data produced by HUD at the 50th percentile as the proxy for relative cost differences in physician office rents. However, as part of our analysis required by section 1848(e)(1)(H)(iv) of the Act, we have now examined the suitability of utilizing 3-year (2006–2008) ACS rental data to serve as a proxy for physician office rents We believe that the ACS rental data provide a sufficient degree of reliability and are an appropriate source on which to base our PE GPCI office rent proxy. We also believe that the ACS data provide a higher degree of accuracy than the HUD data since the ACS is updated annually

and is not based on data collected by the 2000 Census long form. Moreover, it is our understanding that the Census long form, which is utilized to collect the necessary base year rents for the HUD Fair Market Rent (FMR) data, will no longer be available in future years. Therefore, we are proposing to use the available 2006 through 2008 ACS rental data for two bedroom residential units as the proxy for physician office rent. We were not able to collect and analyze 5-year ACS rental data in time for this proposed rule. We may use 5-year ACS data in future rulemaking decisions and would welcome public comments regarding utilization of the 5-year ACS rental data as a proxy for physician office rent.

We believe the ACS data will more accurately reflect geographic variation in the office rent component. As in past GPCI updates, we propose to apply a nationally uniform weight to the office rent component. Although we investigated varying the weight of the office rent index for different localities, we could not find a comprehensive data source that provides office rent information that would allow direct measurement of the variation in this expense among fee schedule areas. Therefore, we are proposing to use the 2006-based MEI weight for fixed capital and utilities as the weight for the office rent category in the PE GPCI, and using the ACS residential rent data to develop the practice expense GPCI value. We welcome public comments on whether there are potential data sources (especially publicly available sources) that would readily provide comprehensive office rent information that would allow us to accurately measure the geographic variation in this expense among fee schedule areas.

(C) Employee Wage Analysis

Accurately evaluating the relative price that physicians pay for labor inputs requires both a mechanism for selecting the occupations to include in the employee wage index and identifying an accurate measure of the wages for each occupation. We received comments during the CY 2011 rulemaking cycle noting that the current employee wage methodology may omit key occupational categories for which cost varies significantly across regions. Commenters suggested including occupations such as accounting, legal, and information technology in the employee wage component of the PE GPCI. To address these concerns, we propose to revise the employee wage index framework within the practice expense (PE) GPCI. Under this new methodology, we would only select occupational categories relevant to a physician's practice. We would use a comprehensive set of wage data from the Bureau of Labor Statistics Occupational Employment Statistics (BLS OES) specific to the offices of physicians industry. Utilizing wage and national cost share weight data from the BLS OES would not only provide a more systematic approach to determining which occupations should be included in the non-physician employee wage category of the PE GPCI, but would also enable us to determine how much weight each occupation should receive within the index.

Due to its reliability, public availability, level of detail, and national scope, we propose to use BLS OES data to estimate both occupation cost shares and hourly wages for purposes of the non-physician employee wage component of the PE GPCI. The OES panel data are collected from approximately 200,000 establishments, and provide employment and wage estimates for about 800 occupations. At the national level, OES provides estimates for over 450 industry classifications (using the 3, 4, and 5 digit North American Industry Classification System (NAICS)), including the Offices of Physicians industry (NAICS 621100). As described in the census, the Offices of Physicians industry comprises establishments of health practitioners having the degree of M.D. (Doctor of Medicine) or D.O. (Doctor of Osteopathy) primarily engaged in the independent practice of general or specialized medicine (except psychiatry or psychoanalysis) or surgery. These practitioners operate private or group practices in their own offices (such as, centers, clinics) or in the facilities of others, such as hospitals or Health Maintenance Organization (HMO) medical centers. The OES data provide significant detail on occupational categories and offer national level cost share estimates for the offices of physicians industry.

We also evaluated available ACS occupational data as a potential data source for the non-physician employee wage PE GPCI subcomponent. Based on the occupations currently used to calculate employee wages, the BLS OES captures occupations with greater relevancy to physician office practices and is a more appropriate data source than the currently available ACS data. However, we intend to study an expanded mix of occupations utilizing 5-year ACS data as that data become available. We welcome comments on our proposal to use the BLS OES specific to the office of physicians industry. In this proposed methodology, we weight each occupation based on its share of total labor cost within the offices of physician industry. Specifically, each occupation's weight is proportional to the product of its occupation's employment share and average hourly wage. In this calculation, we use each occupation's employment level rather than hours worked, because the BLS OES does not contain industry-specific information describing the number of hours worked in each occupation (see: *http://www.bls.gov/oes/current/naics4_621100.htm*). This proposed methodology would account for 90 percent of the total wage share in the office of physicians industry. Additionally, this strategy produces 33 individual occupations with the highest wage shares and would account for many of the occupations commenters have stated were historically excluded from the employee wage calculation (for example, accounting, auditors, and medical transcriptionists), We also welcome public comments on the potential use of the 5-year ACS data to calculate the employee wage component of the PE GPCI.

(D) Purchased Services Analysis

For CY 2012, we are proposing to geographically adjust the labor-related industries within the ''all other services'' and ''other professional expenses'' categories of the MEI. In response to commenters who stated that these purchased services were labor-related and should be adjusted geographically, we agreed to examine this issue further in the CY 2011 final rule with comment period and refrained from making any changes. Based on our subsequent examination of this issue, we believe it would be appropriate to geographically adjust for the labor-related component of purchased services within the ''All Other Services'' and ''Other Professional Expenses'' categories using BLS wage data. In total, there are 63 industries, or cost categories, accounted for within the ''all other services'' and ''other professional services'' categories of the 2006-based MEI. As we established for purposes of the hospital wage index in 74 FR 43845, we define a cost category as labor-related if the cost category is defined as being both labor intensive and its costs vary with, or are influenced by the local labor market. The total proposed purchased services component accounts for 8.095 percent of total practice cost. However, only 5.011 percentage points (of the total 8.095 percentage points assigned to purchased services) are defined as labor-related and thus adjusted for locality cost differences. These 5.011 percentage points represent

cost categories that we believe are labor intensive and have costs that vary with, or are influenced by, the local labor market. The labor-related cost categories include but are not limited to building services (such as janitorial and landscaping), security services, and advertising services. The remaining weight assigned to the non-labor-related industries (3.084 percentage points) represent industries that do not meet the criteria of being labor intensive or having their costs vary with the local labor market.

In order to calculate the labor-related and non-labor-related shares, we would use a similar methodology that is employed in estimating the labor-related share of various CMS market baskets. A more detailed explanation of this methodology can be found under the supporting documents section of the CY 2012 PFS proposed rule web page at *http://www.cms.gov/PhysicianFeeSched/*.

We believe our analysis, during 2010 and this year, of the current methods of establishing PE GPCIs and our evaluation of data that fairly and reliably establish distinctions in the cost of operating a medical practice in the different fee schedule areas meet the statutory requirements of section 1848(e)(1)(H)(iv) of the Act. A more detailed discussion of our analysis of current methods of establishing PE GPCIs and evaluation of data sources is included in Acumen's draft report entitled, ''Proposed Revisions to the Sixth Update of the Geographic Practice Cost Index.'' Acumen's draft report and associated analysis of the proposed GPCI revisions, including the PE GPCIs, will be made publicly available on the CMS Web site. The draft report may be accessed from the PFS Web site at: *http://www.cms.gov/PhysicianFeeSched/* under the ''Downloads'' section of the CY 2012 PFS proposed rule web page.

Additionally, see section VII.B. of this proposed rule for Table 66, which reflects the GAF impacts resulting from these proposals. As the table demonstrates, the primary driver of the CY 2012 impact is the expiration of the work GPCI floor which had produced non-budget neutral increases to the CY 2011 GPCIs for lower cost areas as authorized under the Affordable Care Act the Medicare and Medicaid Extenders Act (MMEA).

(E) Determining the PE GPCI Cost Share Weights

To determine the cost share weights for the CY 2012 GPCIs, we are proposing to use the weights established in the 2006-based MEI. The MEI was rebased and revised in the CY 2011 final rule with comment period to reflect the weighted-average annual price change for various inputs needed to provide physicians' services. As discussed in detail in that section (75 FR 73262 through 73277), the proposed expense categories in the MEI, along with their respective weights, were primarily derived from data collected in the 2006 AMA PPIS for self-employed physicians and selected self-employed non-medical doctor specialties. Since we have historically updated the GPCI cost share weights consistent with the most recent update to the MEI, and because we have addressed commenter concerns regarding the inclusion of the weight assigned to utilities with office rent and geographically adjusted for the labor intensive industries within the ''all other services'' and ''other professional expenses'' MEI categories, we believe it is appropriate to adopt the 2006-based MEI cost share weights.

(i) Practice Expense

For the cost share weight for the proposed CY 2012 PE GPCIs, we would use the 2006-based MEI weight for the PE category of 51.734 percent minus the professional liability insurance category weight of 4.295 percent. Therefore, we propose a cost share weight for the PE GPCIs of 47.439 percent.

(ii) Employee Compensation

For the employee compensation portion of the PE GPCIs, we would use the non-physician employee compensation category weight of 19.153 percent reflected in the 2006-based MEI.

(iii) Office Rent

We are proposing that the weight for the office rent component be revised from 12.209 percent to 10.223 percent. The 12.209 percent office rent GPCI weight was set equal to the 2000-based MEI cost weight for office expenses, which was calculated using the American Medical Association's (AMA) Socioeconomic Monitoring Survey (SMS). The 12.209 percent reflected the expenses for rent, depreciation on medical buildings, mortgage interest, telephone, and utilities. We are proposing to set the GPCI office rent equal to 10.223 percent reflecting the 2006-based MEI cost weights (75 FR 73263) for fixed capital (reflecting the expenses for rent, depreciation on medical buildings and mortgage interest) and utilities. We are no longer including telephone costs in the GPCI office rent cost weight because we believe these expenses do not vary by geographic area.

Consistent with the revised and rebased 2006-based MEI which was adopted in the CY 2011 final rule with comment period (75 FR 73263), we disaggregated the broader office expenses component for the PE GPCI into 10 new cost categories. In this disaggregation, the fixed capital component is the office expense category applicable to the office rent component of the PE GPCI. As discussed in the section dealing with office rent, we are proposing to use 2006–2008 ACS rental data as the proxy for physician office rent. This data represents a gross rent amount and includes data on utilities expenditures. Since it is not possible to separate the utilities component of rent for all ACS survey respondents, it was necessary to combine these two components to calculate office rent and by extension, we propose combining those two cost categories when assigning a weight to the office rent component.

(iv) Purchased Services

As discussed in the previous paragraphs, a new purchased services index was created to geographically adjust the labor-related components of the ''All Other Services'' and ''Other Professional Expenses'' categories of the MEI office expense. In order to calculate the purchased services index, we are proposing to merge the corresponding weights of these two categories to form a combined purchased services weight of 8.095 percent. However, we are proposing to only adjust for locality cost differences of the labor-related share of the industries comprising the ''All Other Services'' and ''Other Professional Expenses'' categories. We have determined that only 5.011 percentage points of the 8.095 percentage points would be adjusted for locality cost differences (5.011 adjusted purchased service + 3.084 non-adjusted purchased services = 8.095 total cost share weight).

(v) Equipment, Supplies, and Other Misc Expenses

To calculate the proposed medical equipment, supplies, and other miscellaneous expenses component, we removed professional liability (4.295 percentage points), non-physician employee compensation (19.153 percentage points), fixed capital/utilities (10.223 percentage points), and purchased services (8.095 percentage points) from the PE category weight (51.734 percent). Therefore, we are proposing a cost share weight for the medical equipment, supplies, and other miscellaneous expenses component of 9.968 percent. Consistent with previous methodology, this component of the PE

GPCI is not adjusted for geographical variation.

(vi) Physician Work and Malpractice GPCIs

Furthermore, we propose to use the physician compensation cost category weight of 48.266 percent as the proposed work GPCI cost share weight; and we propose to use the professional liability insurance weight of 4.295 percent for the malpractice GPCI cost share weight. We believe our analysis and evaluation of the weights assigned to each of the categories within the PE GPCIs satisfies the statutory requirements of section 1848(e)(1)(H)(iv) of the Act.

The proposed cost share weights for the CY 2012 GPCIs are displayed in Table 12. For a detailed discussion regarding the GPCI cost share weights and how the weights account for local and national adjustments, see Acumen's ''Proposed Revisions to the Sixth Update of the Geographic Practice Cost Index'' draft report at (*http://www.cms.gov/PhysicianFeeSched/*)

TABLE 12—COST SHARE WEIGHTS FOR CY 2012 GPCI UPDATE

Expense category	Current cost share weights %	Proposed cost share weights %
Physician Work	52.466	48.266
Practice Expense	43.669	47.439
Employee Compensation	18.654	19.153
Office Rent	12.209	[1] 10.223
Purchased Services	N/A	[2] 8.095
Equipment, Supplies, and Other	12.806	9.968
Malpractice Insurance	3.865	4.295

[1] ACS rental data is a measurement of gross rent and includes utilities. In order to accurately capture the utility measurement present in the ACS two bedroom gross rent data, the cost share weight for utilities is combined with the fixed capital portion to form the office rent index.
[2] The cost share weight for purchased services contains both an adjusted and non-adjusted portion. (5.011 percentage points geographically adjusted purchased services + 3.084 percentage points non-adjusted purchased services).

(F) PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e) (1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in States determined to be frontier States. There are no proposed changes to those states identified as ''frontier States'' for the CY 2012 proposed rule. The qualifying States are reflected in Table 13. In accordance with statute, we will apply a 1.0 GPCI floor for these states in CY 2012.

TABLE 13—FRONTIER STATES UNDER SECTION 1848(E)(1)(I) OF THE ACT

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

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

(2) Summary of CY 2012 PE GPCI Proposal

The PE GPCIs include four components: Employee compensation, office rent, purchased services, and medical equipment, supplies and miscellaneous expenses. Our proposals relating to each of these components are as follows:

• Employee Compensation: We are proposing to geographically adjust the employee compensation using the 2006 through 2008 BLS OES data specific to the offices of physicians industry along with nationwide wage data to determine the employee compensation component of the PE GPCIs. The proposed employee compensation component accounts for 19.153 percent of total practice costs or 40.4 percent of the total PE GPCIs.

• Office Rents: We are proposing to geographically adjust office rent using the 2006–2008 ACS residential rental data for two bedroom units as a proxy for the relative cost differences in physician office rents. In addition, we are proposing to consolidate the utilities into the office rent weight to account for the utility data present in ACS gross rent data. The proposed office rent component accounts for 10.223 percent of total practice cost or 21.5 percent of the PE GPCIs.

• Purchased Services: We are proposing to geographically adjust the labor-related component of purchased services within the ''All Other Services'' and ''Other Professional Expenses ''categories using BLS wage data. The methodology employed to estimate purchased services expenses is based on the same data used to estimate the employee wage index. Specifically, the proposed purchased services framework relies on BLS OES wage data to estimate the price of labor in industries that physician offices frequently rely upon for contracted services. As previously mentioned, the labor-related share adjustment for each industry was derived using a similar methodology as is employed for estimating the labor-related shares of CMS' market baskets.

Furthermore, the weight assigned to each industry within the purchased services index was based on the 2006-based MEI. A more detailed discussion regarding CMS market baskets, as well as the corresponding definitions of a ''labor- related share'' and a ''non -labor-related share'' can be viewed at (74 FR 43845). The total proposed purchased services component accounts for 8.095 percent of total practice cost or 17.1 percent of the PE GPCI. However, the proportion of purchased services that is geographically adjusted for locality cost difference is 5.011 percentage points of the 8.095 percentage points or 10.6 percent of the PE GPCI.

• Medical Equipment, Supplies, and other Miscellaneous Expenses: We continue to believe that items such as medical equipment and supplies have a national market and that input prices do not vary appreciably among geographic areas. As discussed in previous GPCI updates in the CY 2008 and CY 2011 PFS proposed rules, specifically the fifth GPCI update (72 FR 38138) and sixth GPCI update (75 FR 73256), respectively, some price differences may exist, but we believe these differences are more likely to be based on volume discounts rather than on geographic market differences. For example, large physicians' practices may utilize more medical equipment and supplies and therefore may or may not receive volume discounts on some of these items. To the extent that such discounting may exist, it is a function of purchasing volume and not geographic location. The proposed medical equipment, supplies, and miscellaneous expenses component was factored into the PE GPCIs with a component index of 1.000. The proposed medical equipment, supplies, and other miscellaneous expense component account for 9.968 percent of total practice cost or 21.0 percent of the PE GPCI.

c. Malpractice GPCIs

The malpractice GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature ''claims-made'' policies (policies for claims made rather than services furnished during the policy term). We chose claims-made policies because they are the most commonly used malpractice insurance policies in the United States. We used claims-made policy rates rather than occurrence policies because a claims-made policy covers physicians for the policy amount in effect when the claim is made, regardless of the date of event in question; whereas an occurrence policy covers a physician for the policy amount in effect at the time of the event in question, even if the policy is expired. Based on the data we analyzed, we are proposing to revise the cost share weight for the malpractice GPCI from 3.865 percent to 4.295 percent.

3. Payment Localities

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 18 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, 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).

As we have previously noted in the CYs 2008 and 2009 proposed rules (72 FR 38139 and 73 FR 38513), any changes to the locality configuration must be made in a budget neutral manner within a State and can lead to significant redistributions in payments. For many years, we have not considered making changes to localities without the support of a State medical association in order to demonstrate consensus for the change among the professionals whose payments would be affected (since such changes would be redistributive, with some increasing and some decreasing). However, we have recognized that, over time, changes in demographics or local economic conditions may lead us to conduct a more comprehensive examination of existing payment localities.

For the past several years, we have been involved in discussions with physician groups and their representatives about recent shifts in relative demographics and economic conditions. We explained in the CY 2008 PFS final rule with comment period that we intended to conduct a thorough analysis of potential approaches to reconfiguring localities and would address this issue again in future rulemaking. For more information, we refer readers to the CY 2008 PFS proposed rule (72 FR 38139) and subsequent final rule with comment period (72 FR 66245).

As a follow-up to the CY 2008 PFS final rule with comment period, we contracted with Acumen to conduct a preliminary study of several options for revising the payment localities on a nationwide basis. The contractor's interim report was posted on the CMS Web site on August 21, 2008, and we requested comments from the public. The report entitled, ''Review of Alternative GPCI Payment Locality Structures,'' remains accessible from the CMS PFS Web page under the heading ''Interim Study of Alternative Payment Localities under the PFS.'' The report may also be accessed directly from the following link: *http://www.cms.hhs.gov/PhysicianFeeSched/10_Interim_Study.asp#TopOfPage.*

We note that the discussion of PFS payment localities and our preliminary study of alternative payment locality configurations in the CY 2011 PFS proposed rule was intended for informational purposes only. We are not making any proposals regarding the PFS locality configurations for CY 2012.

4. Report From the Institute of Medicine

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) (hospital wage index) of the Act. These adjustments are designed to ensure Medicare payment fees and rates reflect differences in input costs across geographic areas. The factors IOM is evaluating include the—

• 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. health care marketplace, the IOM 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 first report ''Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy'' is a ''Phase I report'' that was released June 1, 2011 and is available on the IOM Web site

http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I–Improving-Accuracy.aspx. It evaluates the accuracy of geographic adjustment factors and the methodology and data used to calculate them. The IOM is conducting further study on GPCI payment issues, and a supplemental report is expected to be issued in the summer of 2011 to address those issues. In its final report, scheduled to be released in the spring of 2012, the IOM will consider the role of Medicare payments in addressing matters such as the distribution of the health care workforce, population health, and the ability of providers to produce high-value, high-quality health care.

The recommendations specifically related to the GPCI included in IOM'sfirst phase report are summarized below:

- 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 5–1: The IOM recommends constructing the geographic practice cost indexes 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 5–2. The committee recommends that the Centers for Medicare and Medicaid Services and the Bureau of Labor Statistics develop an agreement allowing the Bureau of Labor Statistics to analyze confidential data for the Centers for Medicare and Medicaid Services.
- Recommendation 5–3: The committee recommends that a new source of information be identified to obtain data on commercial office rent per square foot.

Because of the timeline related to the release of the PFS proposed rule, we did not have adequate time to fully evaluate these recommendations in the CY 2012 proposed rule. As previously discussed, the IOM will be releasing a supplemental report in the summer of 2011 that will address additional analysis related to the physician work GPCI. We will address the IOM recommendations once we are able to assess the IOM's full recommendations and have given our stakeholders an opportunity to evaluate them. Any changes to the GPCIs in response to the aforementioned IOM recommendations will be proposed through the rulemaking process to allow an opportunity for public notice comment before making revisions.

III. Medicare Telehealth Services for the Physician Fee Schedule

A. Billing and Payment for Telehealth Services

1. 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 provided. 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 provided to an eligible telehealth individual notwithstanding the fact that the individual practitioner providing 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. As specified in BIPA, originating sites are 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)). 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.

2. Current Telehealth Billing and Payment Policies

As noted above, 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 services (DSMT)

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 being furnished via a telecommunications system:

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

Practitioners furnishing Medicare telehealth services are located at a distant site, and they 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 authenticates 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).

B. Requests for Adding Services to the List of Medicare Telehealth Services

As noted above, 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 Medicare telehealth services to one of the following categories:

- 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 use of a telecommunications system to deliver the service produces similar

diagnostic findings or therapeutic interventions as compared with the in-person delivery of the same service. Requestors should submit evidence showing that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the requested service.

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 services (with a minimum of 1 hour of in-person instruction to ensure effective injection training).

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 2011 will be considered for the CY 2013 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *http://www.cms.gov/telehealth/.*

C. Submitted Requests for Addition to the List of Telehealth Services for CY 2012

We received requests in CY 2010 to add the following services as Medicare telehealth services effective for CY 2012: (1) Smoking cessation services; (2) critical care services; (3) domiciliary or rest home evaluation and management services; (4) genetic counseling services; (5) online evaluation and management services; (6) data collection services; and (7) audiology services. The following presents a discussion of these requests, including our proposals for additions to the CY 2012 telehealth list.

1. Smoking Cessation Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add smoking cessation services, reported by 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) to the list of approved telehealth services for CY 2012 on a category 1 basis.

Smoking Cessation services are defined as face-to-face behavior change interventions. We believe the interaction between a practitioner and a beneficiary receiving smoking cessation services is similar to the education, assessment, and counseling elements of individual KDE reported by HCPCS code G0420 (Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per 1 hour), and individual MNT services, 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), all services that are currently on the telehealth list.

Therefore, we are proposing to add CPT codes 99406 and 99407 to the list of telehealth services for CY 2012 on a category 1 basis. Additionally, we are proposing to add HCPCS codes G0436 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes) and G0437 (Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes) to the list of telehealth services for CY 2012 since these related services are similar to the codes for which we received formal public requests.

Consistent with this proposal, we are also proposing to revise our regulations at § 410.78(b) and § 414.65(a)(1) to include these smoking cessation services as Medicare telehealth services.

2. Critical Care Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add critical care service CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes) to the list of approved telehealth services. We previously received this request for the CY 2009 and CY 2010 PFS rulemaking cycles (73 FR 38517, 73 FR 69744–5, 74 FR 33548, and 74 FR 61764) and did not add the codes on a category 1 basis due to the acute nature of the typical patient. We continue to believe that patients requiring critical care services are more acutely ill than those patients typically receiving any service currently on the list of telehealth services. Therefore, we cannot consider critical care services on a category 1 basis.

In the CY 2009 PFS proposed rule (73 FR 38517), we explained that we had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the in-person delivery of critical care services; therefore, we would not add the services on a category 2 basis. Requestors submitted new studies for CY 2012, but none demonstrated that comparable outcomes to a face-to-face encounter can be achieved using telehealth to deliver these services. The studies we received primarily addressed other issues relating to telehealth services. Some studies addressed the cost benefits and cost savings of telehealth services. Others focused on the positive outcomes of telehealth treatment when compared with no treatment at all. One submitted study addressed the equivalency of patient outcomes for telehealth services delivered to patients in emergency rooms, but the study's authors specifically restricted their population to patients whose complaints were not considered to be genuine emergencies. Given that limitation, it seems unlikely that any of these patients would have required critical care services as defined by CPT codes 99291 and 99292.

We note that consultations are included on the list of Medicare telehealth services and may be billed by practitioners furnishing services to critically ill patients. These services are described by the following HCPCS codes: G0425 (Initial inpatient

telehealth consultation, typically 30 minutes communicating with the patient via telehealth), G0426 (Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth), G0427 (Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth), G0406 (Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth), G0407 (Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth), and G0408 (Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth). Critical care services, as reported by the applicable CPT codes and described in the introductory language in the CPT book, consist of direct delivery by a physician of medical care for a critically ill or injured patient, including high complexity decision-making to assess, manipulate, and support vital system functions. Critical care requires interpretation of multiple physiologic parameters and/or application of advanced technologies, including temporary pacing, ventilation management, and vascular access services. The payment rates under the PFS reflect this full scope of physician work. To add the critical services to the telehealth list would require the physician to be able to deliver this full scope of services via telehealth. Based on the code descriptions, we have previously believed that it is not possible to deliver the full range of critical care services without a physical physician presence with the patient.

We note that there are existing Category III CPT codes (temporary codes for emerging services that allow data collection) for remote real-time interactive video conferenced critical care services that, consistent with our treatment of other Category III CPT codes, are not nationally priced under the PFS. The fact that the CPT Editorial Panel created these additional Category III CPT codes suggests to us that these video-conferenced critical care services are not the same as the in-person critical care services requested for addition to the telehealth list.

Because we did not find evidence that use of a telecommunications system to deliver critical care services produces similar diagnostic or therapeutic outcomes as compared with the face-to-face deliver of the services, we are not proposing to add critical care services (as described by CPT codes 99291 and 99292) to the list of approved telehealth services. We reiterate that our decision not to propose to add critical care services to the list of approved telehealth services does not preclude physicians from furnishing telehealth consultations to critically ill patients using the consultation codes that are on the list of Medicare telehealth services.

3. Domiciliary or Rest Home Evaluation and Management Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add the following domiciliary or rest home evaluation and management CPT codes to the telehealth list for CY 2012:

- 99334 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; a problem focused examination; or straightforward medical decision making. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Physicians typically spend 15 minutes with the patient and/or family or caregiver).
- 99335 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Physicians typically spend 25 minutes with the patient and/or family or caregiver).
- 99336 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: a detailed interval history; a detailed examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 40 minutes with the patient and/or family or caregiver).
- 99337 (Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; a comprehensive examination; medical decision making of moderate to high complexity. Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Physicians typically spend 60 minutes with the patient and/or family or caregiver).

A domiciliary or rest home is not permitted under current statute to serve as an originating site for Medicare telehealth services. Therefore, we are not proposing to add domiciliary or rest home evaluation and management services to the list of Medicare telehealth services for CY 2012.

4. Genetic Counseling Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT code 96040 (Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family) to the telehealth list for CY 2012. We note that CPT guidance regarding reporting genetic counseling and education furnished by a physician to an individual directs physicians to evaluation and management (E/M) CPT codes and that services described by CPT code 96040 are provided by trained genetic counselors. Physicians and nonphysician practitioners who may independently bill Medicare for their service and who are counseling individuals would generally report office or other outpatient evaluation and management (E/M) CPT codes for office visits that involve significant counseling, including genetic counseling, and these office visit CPT codes are already on the list of telehealth services. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. These practitioners cannot bill Medicare directly for their professional services and they are also not on the list of practitioners who can furnish telehealth services (specified in section 1834(m)(4)(E) of the Act). As such, we do not believe that it would be necessary or appropriate to add CPT code 96040 to the list of Medicare telehealth services. Therefore, we are not proposing to add genetic counseling

services to the list of Medicare telehealth services for CY 2012.

5. Online Evaluation and Management Services

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

As we explained in the CY 2008 PFS final rule with comment period (72 FR 66371), we assigned a status indicator of ''N'' (Non-covered service) to these services because: (1) These services are non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian).

According to section 1834(m)(2)(A) of the Act, Medicare is required to pay for telehealth services at an amount equal to the amount that a practitioner would have been paid had such service been furnished without the use of a telecommunications system. As such, we do not believe it would be appropriate to make payment for services furnished via telehealth when those services would not otherwise be covered under Medicare. Because CPT code 99444 is currently noncovered, we are not proposing to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2012.

6. Data Collection Services

The American Telemedicine Association and the Marshfield Clinic submitted requests to add CPT codes 99090 (Analysis of clinical data stored in computers (e.g., ECGs, blood pressures, hematologic data)) and 99091(Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, requiring a minimum of 30 minutes of time) to the list of Medicare telehealth services.

As we explained in the CY 2002 PFS final rule with comment period (66 FR 55309), we assigned a status indicator of ''B'' (Payment always bundled into payment for other services not specified) to these services because the associated work is considered part of the pre- and post-service work of an E/M service. We note that many E/M codes are on the list of Medicare telehealth services.

According to section 1834(m)(2)(A) of the Act, Medicare is required to pay for telehealth services an amount equal to the amount that a practitioner would have been paid had such service been furnished without the use of a telecommunications system. Similar to the point noted above for online E/M services, we do not believe it would be appropriate to make separate payment for services furnished via telehealth when Medicare would not otherwise make separate payment for the services. Moreover, we believe the payment for these data collection services should be bundled into the payment for E/M services, many of which are already on the Medicare telehealth list. Because CPT codes 99090 and 99091 are currently bundled, we are not proposing to add data collection services to the list of Medicare telehealth services for CY 2012.

7. Audiology Services

The American Academy of Audiology submitted a request that CMS add services that audiologists provide for balance disorders and hearing loss to the list of Medicare telehealth services. The request did not include specific HCPCS codes. Nevertheless, it is not within our administrative authority to pay audiologists for services furnished via telehealth. The statute authorizes the Secretary to pay for telehealth services only when furnished by a physician or a practitioner as physician or practitioner are defined in sections 1834(m)(4)(D) and (E) of the Act. Therefore, we are not proposing to add services that are primarily provided by audiologists to the list of Medicare telehealth services for CY2012.

D. The Process for Adding HCPCS Codes as Medicare Telehealth Services

Along with its submission of codes for consideration as additions to the Medicare telehealth list for CY 2012, the American Telemedicine Association (ATA) also requested that CMS consider revising the annual process for adding to or deleting services from the list of telehealth services. The existing process, adopted in the CY 2003 PFS rulemaking cycle (67 FR 43862 through 43863 and 67 FR 79988 through 79989), is described in section III.B. of this proposed rule. The following discussion includes a summary of recent requests by the ATA and other stakeholders for changes to the established process for adding services to the telehealth list, an assessment of our historical experience with the current process including the request review criteria, and our proposed refinement to the process for adding services to the telehealth list that would be used in our evaluation of candidate telehealth services beginning for CY 2013.

The ATA asked CMS to consider two specific changes to the process, including:

- Broadening the factors for consideration to include shortages of health professionals to provide in-person services, speed of access to in-person services, and other barriers to care for beneficiaries; and
- Equalizing the standard for adding telehealth services with the standard for deleting telehealth services by adopting a standard that allows services that are safe, effective or medically beneficial when furnished via telehealth to be added to the list of Medicare telehealth services. Similarly, we have received recommendations that CMS place all codes payable under the PFS on the telehealth list and allow physicians and practitioners to make a clinical determination in each case about whether a medically reasonable and necessary service could be appropriately furnished to a beneficiary through telehealth. Under this scenario, stakeholders have argued that CMS would only remove services from the telehealth list under its existing policy for service removal; specifically, that a decision to remove a service from the list of telehealth services would be made using evidence-based, peer-reviewed data which indicate that a specific service is not safe, effective, or medically beneficial when furnished via telehealth (67 FR 79988).

While we share the interests of stakeholders in reducing barriers to health care access faced by some beneficiaries, given that section 1834(m)(2)(F)(ii) of the Act requires the Secretary to establish a process that provides, on an annual basis, for the addition or deletion of telehealth services (and HCPCS codes), as appropriate, we do not believe it would be appropriate to add all services for which payment is made under the PFS to the telehealth list without explicit consideration as to whether the candidate service could be effectively furnished through telehealth. For example, addition of all codes to the telehealth list could result in a number of services on the list that could never be furnished by a physician or nonphysician practitioner who was not physically present with the beneficiary, such as major surgical procedures and interventional radiology services. Furthermore, we do not believe it would

be appropriate to add services to the telehealth list without explicit consideration as to whether or not the nature of the service described by a candidate code allows the service to be furnished as effectively through telehealth as in a face-to-face encounter. Section 1834(m)(2)(A) of the Act requires that the distant site physician or practitioner furnishing the telehealth service must be paid an amount equal to the amount the physician or practitioner would have been paid under the PFS has such service been furnished without the use of a telecommunications system. Therefore, we believe that candidate telehealth services must also be covered when furnished in-person; and that any service that would only be furnished through a telecommunications system would be a new service and, therefore, not a candidate for addition to the telehealth list. In view of these considerations, we will continue to consider candidate additions to the telehealth list on a HCPCS code-specific basis based on requests from the public and our own considerations.

We also believe it continues to be most appropriate to consider candidate services for the telehealth list based on the two mutually exclusive established categories into which all services fall—specifically, services that are similar to services currently on the telehealth list (category 1) and services that are not similar to current telehealth services (category 2). 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 (67 FR 43862). Since CY 2003, we have added 35 services to the telehealth list on a category 1 basis based on public requests and our own identification of such services. We believe it is efficient and valuable to maintain the existing policy that allows us to consider requests for additions to the telehealth list on a category 1 basis and propose to add them to the telehealth list if the existing criteria are met. This procedure expedites our ability to identify codes for the telehealth list that resemble those services already on this list, streamlining our review process and the public request and information-submission process for services that fall into this category. Therefore, we believe that any changes to the process for adding codes to the telehealth list should be considered with respect to category 2 additions, rather than category 1 additions.

Our existing criteria for consideration of codes that would be category 2 additions, specifically those candidate telehealth services that are not similar to any current telehealth services, include an assessment of whether the use of a telecommunications system to deliver the services produces similar diagnostic findings or therapeutic interventions as compared with a face-to-face in-person delivery of the same service (67 FR 43682). In other words, the discrete outcome of the interaction between the clinician and patient facilitated by a telecommunications system should correlate well with the discrete outcome of the clinician-patient interaction when performed face to-face. In the CY 2003 PFS proposed rule (67 FR 43862), we explained that requestors for category 2 additions to the telehealth list should submit evidence that the use of a telecommunications system does not affect the diagnosis or treatment plan as compared to in-person delivery of the service. We indicated that if evidence shows that the candidate telehealth service is equivalent when furnished in person or through telehealth, we would add it to the list of telehealth services. We refer to this criterion in further discussion in this proposed rule as the ''comparability standard.'' We stated in the CY 2003 PFS proposed rule (67 FR 43862) that if we determine that the use of a telecommunications system changes the nature or outcome of the service, for example, as compared with the in-person delivery of the service, we would review the telehealth service addition request as a request for a new service, rather than a different method of delivering an existing Medicare service. For coverage and payment of most services, Medicare requires that a new service must: (1) Fall into a Medicare benefit category; (2) be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act; and (3) not be explicitly excluded from coverage. In such a case, the requestor would have the option of applying for a national coverage determination for the new service.

We believe it is most appropriate to address the ATA and other stakeholder requests to broaden the current factors we consider when deciding whether to add candidate services to the telehealth list—to include factors such as the effects of barriers to in-person care and the safety, effectiveness, or medical benefit of the service furnished through telehealth, as potential refinements to our category 2 criteria. We initially established these category 2 criteria in the interest of ensuring that the candidate services were safe, effective, medically beneficial, and still accurately described by the corresponding codes when delivered via telehealth, while also ensuring that beneficiaries furnished telehealth services receive high quality care that is comparable to in-person care. We believed that the demonstration of comparable clinical outcomes (diagnostic findings and/or therapeutic interventions) from telehealth and in-person services would prove to be the best indicator that all of these conditions were met. While we continue to believe that safety, effectiveness, and medical benefit, as well as accurate description of the candidate telehealth services by the CPT or HCPCS codes, are necessary conditions for adding codes to the list of Medicare telehealth services, our recent experience in reviewing public requests for telehealth list additions and our discussions with stakeholders regarding contemporary medical practice and potential barriers to care, have led us to conclude that the comparability standard for category 2 requests should be modified.

In our annual evaluation of category 2 requests since we adopted the process for evaluating additions to the telehealth list almost 10 years ago, we have consistently observed that requestors have difficulty demonstrating that clinical outcomes of a service delivered via telehealth are comparable to the outcomes of the in-person service. The medical literature frequently does not include studies of the outcomes of many types of in-person services that allow for comparison to the outcomes demonstrated for candidate telehealth services. Furthermore, we know that in some cases the alternative to a telehealth service may be no service rather than an in-person service. The comparability standard may not sufficiently allow for the opportunity to add candidate services to the telehealth list that may be safe, effective, and medically beneficial when delivered via telehealth, especially to beneficiaries who experience significant barriers to in-person care. While we continue to believe that beneficiaries receiving services through telehealth are deserving of high quality health care and that in-person care may be very important and potentially preferable for some services when in-person care is possible, we are concerned that we have not added any services to the telehealth list on a category 2 basis as a result of our reviews. While some candidate services appear to have the potential for clinical benefit when furnished through

telehealth, the requests have not met the comparability standard.

Therefore, we are proposing to refine our category 2 review criteria for adding codes to the list of Medicare telehealth services beginning in CY 2013 by modifying the current requirement to demonstrate similar diagnostic findings or therapeutic interventions with respect to a candidate service delivered through telehealth compared to in-person delivery of the service (the comparability standard). We propose to establish a revised standard of demonstrated clinical benefit (the clinical benefit standard) when the service is furnished via telehealth. To support our review using this revised standard, we would ask requestors to specify in their request how the candidate telehealth service is still accurately described by the corresponding HCPCS or CPT code when delivered via telehealth as opposed to in-person.

We are proposing that our refined criteria for category 2 additions would be as follows:

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests would include 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. Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient.

The evidence submitted 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. 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.

We believe the adoption of this clinical benefit standard for our review of candidate telehealth services on a category 2 basis is responsive to the requests of stakeholders that we broaden the factors taken into consideration to include barriers to care for beneficiaries. It allows us to consider the demonstrated clinical benefit of telehealth services for beneficiaries who might otherwise have no access to certain diagnostic or treatment services. Furthermore, we believe the focus on demonstrated clinical benefit in our review of category 2 requests for addition to the telehealth lists is equivalent to our standard for deleting services from the telehealth list that rests upon evidence that a service is not safe, not effective, or not medically beneficial. Finally, we believe the proposed clinical benefit standard for our review of candidate telehealth services on a category 2 basis is fully consistent with our responsibility to ensure that telehealth services are safe, effective, medically beneficial, and still accurately described by the corresponding codes that would be used for the services when delivered in-person.

We are soliciting public comments on this proposed refinement to our established process for adding codes to the telehealth list, including the information that requestors should furnish to facilitate our full review of requests in preparation for the next calendar year's rulemaking cycle. We will respond to comments on our proposal and finalize any changes to the process for addition codes to the telehealth list in the CY 2012 PFS final rule with comment period. We would use the revised category 2 review criteria to review requested additions to the telehealth list submitted during CY 2011 and under consideration for CY 2013.

E. Telehealth Consultations in Emergency Departments

We have recently been asked to clarify instructions regarding appropriate reporting of telehealth services that, prior to our policy change regarding consultation codes, would have been reported as consultations furnished to patients in an emergency department. When we eliminated the use of all consultation codes beginning in CY 2010, we instructed practitioners, when furnishing a service that would have been reported as a consultation service, to report the E/M code that is most appropriate to the particular service for all office/outpatient or inpatient visits. Since section 1834(m) of the Act includes ''professional consultations'' (including the initial inpatient consultation codes ''as subsequently modified by the Secretary'') in the definition of telehealth services, we established several HCPCS codes to describe the telehealth delivery of initial inpatient consultations. For inpatient hospital and skilled nursing facility care telehealth services, we instructed practitioners to use the inpatient telehealth consultation G-codes listed in table 14 to report those telehealth services (74 FR 61763, 61774). However, we neglected to account for the fact that E/M emergency department visit codes (99281–99285) are not on the telehealth list. As such, there has not been a clear means for practitioners to bill a telehealth consultation furnished in an emergency department. In order to address this issue, we are proposing to change the code descriptors for the inpatient telehealth consultation G-codes to include emergency department telehealth consultations effective January 1, 2012. However, we are seeking public comment regarding other options, including creating G-codes specific to these services when furnished to patients in the emergency department.

TABLE 14—INPATIENT TELEHEALTH CONSULTATION G–CODES

HCPCS Code	CY 2011 Long code descriptor
G0425	Initial inpatient telehealth consultation, typically 30 minutes communicating with the patient via telehealth.
G0426	Initial inpatient telehealth consultation, typically 50 minutes communicating with the patient via telehealth.
G0427	Initial inpatient telehealth consultation, typically 70 minutes or more communicating with the patient via telehealth.
G0406	Follow-up inpatient telehealth consultation, limited, physicians typically spend 15 minutes communicating with the patient via telehealth.

TABLE 14—INPATIENT TELEHEALTH CONSULTATION G–CODES—Continued

HCPCS Code	CY 2011 Long code descriptor
G0407	Follow-up inpatient telehealth consultation, intermediate, physicians typically spend 25 minutes communicating with the patient via telehealth.
G0408	Follow-up inpatient telehealth consultation, complex, physicians typically spend 35 minutes or more communicating with the patient via telehealth.

IV. Other Provisions of the Proposed Regulation

A. 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, 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)

Section 1847A(d)(1) of the Act states that ''The Inspector General of HHS shall conduct studies, which may include surveys, to determine the widely available market prices (WAMP) of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.'' Section 1847A (d)(2) of the Act states, ''Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the ASP under this section for drugs and biologicals with—

- The widely available market price (WAMP) for these drugs and biologicals, (if any); and
- The average manufacturer price (AMP) (as determined under section 1927(k) (1) of the Act) for such drugs and biologicals.''

Section 1847A(d)(3)(A) of the Act states that, ''The Secretary may disregard the ASP for a drug or biological that exceeds the WAMP or the AMP for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).'' Section 1847A(d)(3)(C) of the Act states that if the Inspector General (OIG) finds that the ASP for a drug or biological is found to have exceeded the WAMP or AMP by this threshold percentage, the OIG ''shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological, the lesser of—

- the widely available market price for the drug or biological (if any); or
- 103 percent of the average manufacturer price as determined under section 1927(k)(1) of the Act for the drug or biological.''

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 establishes that the applicable threshold percentage is ''the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify 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 current applicable threshold percentage.

For CY 2011, we proposed to specify two separate adjustments to the applicable threshold percentages. When making comparisons to the WAMP, we proposed the applicable threshold percentage to remain at 5 percent. The applicable threshold percentage that we proposed for the AMP is addressed below in this section of the preamble. The latest WAMP comparison was published in 2008, and the OIG is continuing to perform studies comparing ASP to WAMP. Based on available OIG reports that have been published comparing WAMP to ASP, we did not have sufficient information at the time to determine that the 5 percent threshold percentage is inappropriate and should be changed. As a result, we believed that continuing the 5 percent applicable threshold percentage for the WAMP was appropriate for CY 2011. Therefore, we proposed to revise § 414.904(d)(3) to specify the 5 percent WAMP threshold for CY 2011. After soliciting and reviewing comments, we finalized our proposal to continue the 5 percent WAMP threshold for CY 2011 (75 FR 73469).

For CY 2012, we again propose to specify a separate adjustment to the applicable threshold percentage for WAMP comparisons. When making comparisons to the WAMP, we propose the applicable threshold percentage to remain at 5 percent. We still do not have sufficient information to determine that the 5 percent threshold percentage is inappropriate and, as a result, we believe that continuing the 5 percent applicable threshold percentage for the WAMP is appropriate for CY 2012. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73470), we understand that there are complicated operational issues associated with this policy. 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 regarding such, including the opportunity to provide input with regard to the processes for substituting the WAMP for the ASP.

2. AMP Threshold and Price Substitutions

As mentioned previously in section V.A.1. of this proposed rule, when making comparisons of ASP to AMP, the applicable threshold percentage for CY 2005 was specified in statute as 5 percent. Section 1847A(d)(3) of the Act allows the Secretary to specify adjustments to this threshold percentage for years subsequent to 2005. For CY 2006 (70 FR 70222), CY 2007 (71 FR 69680), CY 2008 (72 FR 66258), CY 2009 (73 FR 69752), and CY 2010 (74 FR 61904), the Secretary made no adjustments to the threshold percentage; it remained at 5 percent.

For CY 2011, we proposed, with respect to AMP substitution, to apply the applicable percentage subject to certain adjustments such that substitution of AMP for ASP will only be made 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. We further proposed to apply the applicable AMP

threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of National Drug Codes (NDCs) for a billing code (that is, ''complete'' AMP data).

Furthermore, we proposed a price substitution policy to substitute 103 percent of AMP for 106 percent of ASP for both multiple and single source drugs and biologicals as defined respectively at section 1847(A)(c)(6)(C) and (D) of the Act. Specifically, we proposed that this substitution:

- Would occur when the applicable threshold percentage has been met for two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter.
- Would permit for a final comparison between the OIG's volume-weighted 103 percent of AMP for a billing code (calculated from the prior quarter's data) and the billing code's volume weighted 106 percent ASP (as calculated by CMS for the current quarter) to avoid a situation in which the AMP-based price substitution would exceed that quarter's ASP; and
- That the duration of the price substitution would last for only one quarter.

We also sought comment on other issues related to the comparison between ASP and AMP, such as the following:

- Any effect of definitional differences between AMP and ASP, particularly in light of the definition of AMP as revised by section 2503 of the Affordable Care Act.
- The impact of any differences in AMP and ASP reporting by manufacturers on price substitution comparisons.
- Whether and/or how general differences and similarities between AMP and manufacturer's ASP would affect comparisons between these two.

In the CY 2011 PFS final rule with comment, we did not finalize our proposed adjustments to the 5 percent AMP threshold or our price substitution policy because of legislative changes, regulatory changes, and litigation that affected this issue. Specifically—

- A preliminary injunction issued by the United States District Court for the District of Columbia in *National Association of Chain Drug Stores et al.* v. *Health and Human Services*, Civil Action No. 1:07–cv–02017 (RCL) was still in effect;
- We were continuing to expect to develop regulations to implement section 2503 of the Affordable Care Act, which amended the definition of AMP, and section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Improvement Act (Pub. L. 111–226) as enacted on August 10, 2010, which further amended section 1927(k) of the Act;
- We proposed to withdraw certain provisions of the AMP final rule published on July 17, 2007 (75 FR 54073).

As a result, we finalized the portion of our proposal that sets the AMP threshold at 5 percent for CY 2011 and revised the regulation text accordingly (75 FR 73470).

The preliminary injunction was vacated by the United States District Court for the District of Columbia on December 15, 2010. Currently, we continue to expect to develop regulations to implement section 2503 of the Affordable Care Act and section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Improvement Act. However, these statutory amendments became effective on October 1, 2010 without regard to whether or not final regulations to carry out such amendments have been promulgated by such date. Moreover, our Medicaid final rule published on November 15, 2010 finalized regulations requiring manufacturers to calculate AMP in accordance with section 1927(k)(1) of the Act (75 FR 69591). Since statutory and regulatory provisions exist and are currently utilized by manufacturers for the calculation and submission of AMP data, we are revisiting the AMP threshold and price substitution issues.

a. AMP Threshold

Section 1847A(d)(3) of the Act allows the Secretary to specify adjustments to this threshold percentage for years subsequent to 2005, and to specify the timing for any price substitution. Therefore, for CY 2012, with respect to AMP substitution, we propose to apply the applicable percentage subject to certain adjustments. Specifically, a price 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.

In general, the ASP methodology reflects average market prices for Part B drugs for a quarter. The ASP is based on the average sales price to all purchasers for a calendar quarter; the AMP, in turn, represents the average price paid by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturers. Accordingly, while the ASP payment amount for a billing code may exceed its AMP for that billing code for any given quarter, this may reflect only a temporary fluctuation in market prices that would be corrected in a subsequent quarter. We believe this fluctuation is demonstrated by how few billing codes exceed the applicable threshold percentage over multiple quarters. For example, in the Inspector General's report ''Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009,'' only 11 of 493 examined billing codes exceeded the applicable threshold percentage over multiple quarters (OEI–03–10–00380). We are concerned that substitutions based on a single quarter's ASP to AMP comparison will not appropriately or accurately account for temporary fluctuations. We believe that applying this threshold percentage adjusted to reflect data from multiple quarters will account for continuing differences between ASP and AMP, and allow us to more accurately identify those drugs that consistently trigger the substitution threshold and thus warrant price substitution.

We further propose to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, ''complete'' AMP data). Prior to 2008, the OIG calculated a volume-weighted AMP and made ASP and AMP comparisons only for billing codes with such ''complete'' AMP data. In such comparisons, a volume-weighted AMP for a billing code was calculated when NDC-level AMP data was available for the same NDCs used by us to calculate the volume-weighted ASP. Beginning in the first quarter of 2008, the OIG also began to make ASP and AMP comparisons based on ''partial'' AMP data (that is, AMP data for some, but not all, NDCs in a billing code). For these comparisons, the volume-weighted AMP for a billing code is calculated even when only such limited AMP data is available. That is, the volume-weighted AMP calculated by the Inspector General is based on fewer NDCs than the volume-weighted ASP calculated by CMS. Moreover, volume-weighted ASPs are not adjusted by the Inspector General to reflect the fewer number of NDCs in the volume-weighted AMP.

Because the OIG's partial AMP data comparison did not reflect all the NDCs used in our volume-weighted ASP calculations, we discussed our concern about using the volume-weighted AMP in the CY 2011 PFS proposed rule. We believed that such AMP data may not

adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate volume-weighted prices. Payment amount reductions that result from potentially inaccurate substitutions may impact physician and beneficiary access to drugs. Therefore, consistent with our authority as set forth in section 1847A(d)(1) and (3) of the Act, we proposed in the CY 2011 PFS proposed rule that the substitution of 103 percent of AMP for 106 percent of ASP should be limited to only those drugs with ASP and AMP comparisons based on the same set of NDCs.

In response to our CY 2011 proposed rule, the OIG changed its methodology for ''partial'' AMP data comparisons beginning with its report titled ''Comparison of First-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010.'' Specifically, in addition to calculating a volume-weighted AMP based on ''partial'' data and identifying billing codes that exceeded the price substitution threshold, the OIG began to replace each missing NDC-level AMP with corresponding NDC-level ASP data. The OIG then calculated a volume-weighted AMP for the billing code. If the volume-weighted AMP continued to exceed the price substitution threshold, the report attributed this to an actual difference between ASPs and AMPs in the marketplace (OEI–03–10–00440).

We appreciate that the Inspector General has acknowledged the importance of protecting beneficiary and physician access in its methodology change. However, section 1847(A)(d)(2)(B) of the Act specifically indicates that the comparison be made to AMP as determined under section 1927(k)(1) of the Act. Moreover, we continue to be concerned that comparisons based on partial AMP data may not adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate volume-weighted prices. Therefore, for CY 2012, we propose to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, ''complete'' AMP data). Furthermore, we are proposing to revise § 414.904(d)(3) to reflect corresponding regulatory text changes, and we welcome comments on all aspects of this proposal.

b. AMP Price Substitution

(1) Inspector General Studies

Section 1847A(d) of the Act requires the Inspector General to conduct studies of the widely available market price for drugs and biologicals to which section 1847A of the Act applies. However, it does not specify the frequency of when such studies should be conducted. The Inspector General has conducted studies comparing AMP to ASP for essentially each quarter since the ASP system has been implemented. Since 2005, the OIG has published 23 reports pertaining to the price substitution issue (see Table 15), of which 21 have identified billing codes with volume-weighted ASPs that have exceeded their volume-weighted AMPs by the applicable threshold percentage.

TABLE 15—PUBLISHED OIG REPORTS ON PRICE SUBSTITUTIONS

Date	Report title
5/2011	Comparison of Third–Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2011 (OEI–03–11–00160).
4/2011	Comparison of Average Sales Prices and Average Manufacturer Prices: An overview of 2009 (OEI–03–10–00380).
2/2011	Comparison of Second–Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010 (OEI–03–11–00030).
11/2010	Comparison of First–Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010 (OEI–03–10–00440).
7/2010	Comparison of Fourth–Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2010 (OEI–03–10–00350).
4/2010	Comparison of Third–Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010 (OEI–03–10–00150).
2/2010	Comparison of Average Sales Prices and Average Manufacturer Prices: An overview of 2008 (OEI–03–09–00350).
1/2010	Comparison of Second–Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2009 (OEI–03–09–00640).
8/2009	Comparison of First–Quarter 2009 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2009 (OEI–03–09–00490).
8/2009	Comparison of Fourth–Quarter 2008 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2009 (OEI–03–09–00340).
4/2009	Comparison of Third-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for first Quarter 2009 (OEI–03–09–00150).
2/2009	Comparison of Second-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2008 (OEI–03–09–00050).
12/2008	Comparison of First-Quarter 2008 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2008 (OEI–03–08–00530).
12/2008	Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007 (OEI–03–08–00450).
8/2008	Comparison of Fourth–Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2008 (OEI–03–08–00340).
7/2008	A comparison of average sales price to widely available market prices for inhalation drugs (OEI–03–07–00190).
5/2008	Comparison of Third–Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2008 (OEI–03–08–00130).
12/2007	Comparison of Second–Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2007 (OEI–03–08–00010).
9/2007	Comparison of First–Quarter 2007 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2007 (OEI–03–07–00530).
7/2007	Comparison of Third–Quarter 2006 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007 (OEI–03–07–00140).

TABLE 15—PUBLISHED OIG REPORTS ON PRICE SUBSTITUTIONS—Continued

Date	Report title
7/2006	Comparison of Fourth–Quarter 2005 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006 (OEI–03–06–00370).
6/2006	A Comparison of Average Sales Price to Widely Available Market Prices: Fourth Quarter 2005 (OEI–03–05–00430).
4/2006	Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Price to Average Manufacturer Prices (OEI–03–04–00430).

In the latest quarterly report comparing AMP to ASP, titled ''Comparison of Third-Quarter 2010 Average Sales Price and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2011'' (OEI–03–11–00160), the Inspector General found that of 365 billing codes with complete AMP data in the third quarter of 2010, only 14 met the 5 percent threshold; that is, ASP exceeded AMP by at least 5 percent. 8 of these 14 billing codes also exceeded the AMP by at least 5 percent in one or more of the previous four quarters; only two drugs had ASPs that exceeded the 5 percent threshold in all four quarters under review. This Inspector General report further indicates that, ''If reimbursement amounts for all 14 codes with complete AMP data had been based on 103 percent of the AMPs during the first quarter of 2011, we estimate that Medicare expenditures would have been reduced $10.3 million in that quarter alone.'' The savings found by the Inspector General constitute potential savings for the Medicare program and beneficiaries.

(2) Proposal

As discussed previously, section 1847A(d)(3) of the Act provides authority for us to determine the applicable percentage subject to ''such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.'' We also have authority to specify the timing of any ASP substitution. Consistent with this authority, we are proposing a policy to substitute 103 percent of AMP for 106 percent of ASP where the applicable percentage threshold has been satisfied for the two consecutive quarters immediately prior to the current pricing quarter, or for three of the previous four quarters immediately prior to the current pricing quarter. This policy would apply to single source drugs and biologicals, multiple source drugs, and biosimilar biological products as defined at section 1847A(c)(6)(C), (D), and (H) of the Act.

Because of the lack of data regarding WAMP to ASP comparisons, we are explicitly excluding WAMP from this price substitution proposal, though we are proposing to maintain the WAMP threshold at 5 percent for CY 2012 in section V.A.1. of this rule. We believe that the proposed policy reflects market-related pricing changes and focuses on those drugs that consistently exceed the applicable percentage threshold over multiple quarters. Unlike the OIG's AMP studies, the published WAMP studies do not show whether the prices for the examined groups of drugs consistently exceed the applicable percentage threshold across multiple quarters like the AMP studies. We will consider proposing a policy for the substitution of WAMP at a later date.

(3) Timeframe for and Duration of Price Substitutions

As stated in § 414.804(a)(5), a manufacturer's average sales price must be submitted to CMS within 30 days of the close of the quarter. We then calculate an ASP for each billing code in accordance with the process outlined at § 414.904. Then, as described in our CY 2005 PFS final rule (69 FR 66300), we implement these new prices through program instructions or otherwise at the first opportunity after we receive the data, which is the calendar quarter after receipt.

Section 1847A(d)(3)(C) of the Act indicates that a price substitution would be implemented ''effective as of the next quarter'' after the OIG has informed us that the ASP for a drug or biological exceeds its AMP by the applicable percentage threshold. The OIG does not receive new ASPs for a given quarter until after we have finalized our calculations for the quarter. Also, the results of the OIG's pricing comparisons are not available until after the ASPs for a given quarter have gone into effect. Therefore, we anticipate that there will be a three-quarter lag for substituted prices from the quarter in which manufacturer sales occurred, though this will depend in great part upon the timeframe in which we obtain comparison data from the OIG. Table 16 provides an example of this timeframe.

TABLE 16—EXAMPLE PRICE SUBSTITUTION TIMEFRAME

	Q2–11	Q3–11	Q4–11	Q1–12
ASP Process	Manufacturer sells drug.	Manufacturer submits Q2–11 pricing data. CMS calculates ASP payment limits for Q4–11 and publishes Q4–11 payment limits.	Q4–11 payment limits apply. CMS calculates ASP payment limits for Q1–12. Compares calculated payment limits to OIG substitute prices. Publishes Q1–12 prices that may include OIG substitute prices.	Q1–12 payment limits apply, including any adjusted payment limit resulting from the price substitution.
OIG Process		OIG receives Q4–11 payment limits from CMS and compares them to Q2–11 volume-weighted AMP data.	OIG notifies CMS of HCPCS for which Q4–11 ASP exceeds Q2–11 AMP by the applicable percentage threshold.	

Given this lag in time, the ASP for a billing code may have decreased since the OIG's comparison. Therefore, consistent with our authorities in section 1847A(d)(3) of the Act and our desire to provide accurate payments consistent with these provisions, we believe that the timing of any substitution policy should permit a final

comparison between the OIG's volume-weighted 103 percent AMP for a billing code (calculated from the data from sales three quarters prior) and the billing code's volume-weighted 106 percent ASP (as calculated by CMS for the upcoming quarter). In Table 16, for example, this comparison would be done between the HCPCS payment limits calculated for Q1–12, and the OIG's volume-weighted AMPs from their examination of Q4–11 payment limits. This final comparison would assure the Secretary that the 106 percent ASP payment limit for the current pricing quarter continues to exceed 103 percent of the OIG's calculated AMP in order to avoid a situation in which the Secretary would inadvertently raise the Medicare payment limit through this price substitution policy. We specifically request comments on this proposal.

ASP payment limits are calculated on a quarterly basis as per section 1847A(c)(5)(A) of the Act, and we are particularly mindful that the ASP-based payment allowance for a billing code may change from quarter to quarter. As such, we propose that any price substitution based on the comparison that triggered its application would last for one quarter. We note that in a subsequent quarter, the OIG may identify that a volume-weighted ASP continues to exceed the volume-weighted AMP for a billing code that previously triggered a price substitution. In this scenario, if the criteria for the price substitution policy are met, we would substitute 103 percent of the OIG's updated volume-weighted AMP for that billing code.

Overall, we believe that our proposal as previously outlined to substitute 103 percent of AMP for 106 percent of ASP provides us with a viable mechanism for generating savings for the Medicare program and its beneficiaries because it will allow Medicare to pay based on lower market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Moreover, it will enable us to address a programmatic vulnerability identified by the OIG. We welcome comments on all aspects of our proposal.

In the CY 2011 proposed rule, we sought comment on other issues related to the comparison between ASP and AMP, specifically:

- Any effect of definitional differences between AMP and ASP, particularly in light of the definition of AMP as revised by section 2503 of the Affordable Care Act.
- The impact of any differences in AMP and ASP reporting by manufacturers on price substitution comparisons.
- Whether and/or how general differences and similarities between AMP and manufacturer's ASP would affect comparisons between these two.

For the CY 2012 proposed rule, we again seek comment on other matters pertaining to this issue.

3. ASP Reporting Update

a. ASP Reporting Template Update

For purposes of this part, unless otherwise specified, the term ''drugs'' will hereafter refer to both drugs and biologicals. Sections 1847A and 1927(b) of the Act specify quarterly ASP data reporting requirements for manufacturers. Specific ASP reporting requirements are set forth in section 1927(b)(3) of the Act. For the purposes of reporting under section 1847A of the Act, the term ''manufacturer'' is defined in section 1927(k)(5) of the Act and means any entity engaged in the following: Production; preparation, propagation, compounding, conversion or processing of prescription drug products; either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in certain wholesaler activities are required to report ASP data for those drugs that they manufacture. Note that the definition of manufacturers for the purposes of ASP data reporting includes repackagers.

Section 1927(b)(3)(A)(iii) of the Act specifies that manufacturers must report their average sales price and the number of units by NDC. As established by 42 CFR part 414 subpart J, manufacturers are required to report data at the NDC level, which includes the following elements: (1) The manufacturer ASP; (2) the Wholesale Acquisition Cost (WAC) in effect on the last day of the reporting period; (3) the number of units sold; and (4) the NDC. The reported ASP data are used to establish the Medicare payment amounts.

Section 1927(b)(3)(A)(iii)(II) of the Act specifies that the manufacturer must report the WAC, if it is required in order for payment to be made under section 1847A of the Act. In the 2004 IFC that implemented the ASP reporting requirements for Medicare Part B drugs and biologicals (66 FR 17935), we specified that manufacturers must report the ASP data to CMS using our Addendum A template. In 2005, we expanded the template to include WAC and additional product description details (70 FR 70221). We also initiated additional changes to the template in 2008 (73 FR 76032).

In order to facilitate more accurate and consistent ASP data reporting from manufacturers, we are now proposing additional revisions to the Addendum A template. Specifically, we propose to revise existing reporting fields and add new fields to the Addendum A template, as follows:

- To split the current NDC column into three separate reporting fields, corresponding to the three segments of an NDC.
- To add a new field to collect an Alternate ID for products without an NDC.
- To expand the current FDA approval number column to account for multiple entries and supplemental numbers.

We have also added a macro to the Addendum A template that will allow manufacturers to validate the format of their data prior to submission. This will help verify that data are complete and submitted to CMS in the correct format, thereby minimizing time and resources spent on identifying mistakes or errors. We note that the use of this macro does not preclude or supersede manufacturers' responsibility to provide accurate and timely ASP data in accordance with the reporting obligation under section 1927(b)(3) of the Act. We also note that manufacturers who misrepresent or fail to report manufacturer ASP data will remain subject to civil monetary penalties, as applicable and described in sections 1847A and 1927(b) of the Act and codified in regulations at § 414.806.

b. Reporting of ASP Units and Sales Volume for Certain Products

As required by 42 CFR part 414 subpart J, manufacturers report ASP price and volume data at the NDC level. This is appropriate for most drug and biological products because an NDC is usually associated with a consistent amount of product that is being sold. Our experience with manufacturer reporting of ASPs has revealed that a limited number of drug products, as defined by an NDC, might contain a variable amount of active ingredient. This situation is common for plasma derived clotting factors; for example, we are aware of one product where a vial described as nominally containing 250 international units (IUs) of clotting factor activity might actually contain

between 220 and 400 IUs. Although the exact factor activity is specified on the label, the amount of IUs contained in an NDC might vary between manufacturing lots. For these types of products, it is possible that vials with the same NDC but different amounts of clotting factor activity (as measured in IUs) might be sold during the same ASP reporting period. For drugs paid under Medicare Part B, such variability in the amount of drug product within an NDC appears to apply mostly to clotting factors that are prepared from plasma sources; it also applies to a few other products, including a plasma protein product used to treat antitrypsin deficiency.

As stated in the Section 1847A(b)(2) of the Act, for years after 2004, the Secretary has the authority to ''establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement.'' There are limited situations when ASP price and volume reporting by product NDC may affect the accuracy of subsequent pricing calculations done by us, for example, when an NDC is associated with a variable amount of drug product as described in the paragraph previously. We believe that in such cases it is appropriate to amend the definition of the ASP unit associated with the NDC that is reported to us by manufacturers for the purposes of calculating ASP. Under the authority in the section 1847A(b)(2) of the Act, we propose that we will maintain a list of HCPCS codes for which manufacturers report ASPs for NDCs on the basis of a specified unit. The specified unit will account for situations where labeling indicates that the amount of drug product represented by an NDC varies. Our initial list appears in Table 17 and is limited to items with variable amounts of drug product per NDC as described previously. However, we propose to update this list as appropriate through program instruction or otherwise because we believe that the ability to make changes in a subregulatory manner will provide us with the flexibility to quickly and appropriately react to sales and marketing practices for specific drug products, including the introduction of new drugs or drug products. We plan to amend the list as necessary and to keep updates on the CMS ASP Web site at: *http://www.cms.gov/McrPartBDrugAvgSalesPrice/01_overview.asp.* Our proposals would be effective for ASP reports received on or after January 1, 2012 and would be reflected in our April 1, 2012 quarterly update.

In conjunction with the proposals in the preceding paragraph and the expectation that nearly all ASP price and sales volume reporting will continue to be at the NDC level (that is, the reported ASP sales and volume will be associated with a non-variable amount that is represented by the NDC), we are also proposing a clarification to existing regulation text at § 414.802. Current regulation text states that ''Unit means the product represented by the 11-digit National Drug Code.'' We propose to update the definition to account for situations when an alternative unit of reporting must be used; the definition of the term unit will continue to be based on reporting of ASP data per NDC unless otherwise specified by CMS to account for situations where the amount of drug product represented by an NDC varies.

TABLE 17—HCPCS CODES FOR WHICH ASP REPORTING IS DONE IN UNITS OF MEASURE OTHER THAN AN NDC

2011 Code	2011 Long descriptor	Proposed reporting unit
J0256	INJECTION, ALPHA 1—PROTEINASE INHIBITOR—HUMAN, 10 MG	1MG
J1680	INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 100 MG	1MG
J7184	INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, PER 100 IU VWF:RCO	1 IU VWF:RCO
J7185	INJECTION, FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) (XYNTHA), PER I.U	1 IU
J7186	INJECTION, ANTIHEMOPHILIC FACTOR VIII/VON WILLEBRAND FACTOR COMPLEX (HUMAN), PER FACTOR VIII I.U.	1 IU
J7187	INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMATE–P), PER IU VWF:RCO	1 IU VWF:RCO
J7190	FACTOR VIII (ANTIHEMOPHILIC FACTOR, HUMAN) PER I.U	1 IU
J7192	FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U., NOT OTHERWISE SPECIFIED.	1 IU
J7193	FACTOR IX (ANTIHEMOPHILIC FACTOR, PURIFIED, NON–RECOMBINANT) PER I.U	1 IU
J7194	FACTOR IX, COMPLEX, PER I.U	1 IU
J7195	FACTOR IX (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U	1 IU
J7197	ANTITHROMBIN III (HUMAN), PER I.U	1 IU
J7198	ANTI–INHIBITOR, PER I.U. INJECTION, ANTITHROMBIN RECOMBINANT, 50 I.U	1 IU

The instructions for reporting products with variable amounts of drug product, along with general instructions on completing the revised ASP Data Form (Addendum A), will be delineated in a User Guide that will be available on the ASP Web site. In the user guide, we will also be revising our instructions for the reporting of dermal grafting products as follows:

- If an NDC is not associated with a dermal grafting product, manufacturers should enter the UPC or other unique identifier (such as an internal product number) in the alternate ID column.
- Manufacturers should report ASP prices and sales volumes for dermal grafting products in units of area by square centimeter. The User Guide will be available on the CMS ASP Web site at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp.* The Web site will also contain the revised ASP Data Form (Addendum A) and examples of how ASP data must be reported and formatted for submission.

We would also like to remind manufacturers that additional information about reporting ASP data to us is available (for examples, see the following: (69 FR 17936), (69 FR 66299), (70 FR 70215), (71 FR 69665), (72 FR 66256), (73 FR 69751), and (74 FR 61904)). Also, a link to the ASP Frequently Asked Questions (FAQs) is posted in the ''Related Links Inside CMS'' section of the ASP Overview Web page. We welcome comments on the ASP reporting proposals that are described in this section.

B. 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 manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act. 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'' and 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 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 budget neutrality. 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 to Medicare was an $114 million increase in costs. 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 to Medicare 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, including 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.

We are continuing the implementation of the required budget neutrality adjustment by recouping $10 million in CY 2012. Our Office of the Actuary estimates chiropractic expenditures in CY 2012 to be approximately $470 million based on actual Medicare spending for chiropractic services for the most recent available year. To recoup $10 million in CY 2012, the payment amount under the PFS for the chiropractic CPT codes (that is, 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.

C. Proposed Productivity Adjustment for the Ambulatory Surgical Center Payment System, and the Ambulance, Clinical Laboratory and DMEPOS Fee Schedules

Section 3401 of the Affordable Care Act requires that the update factor under certain payment systems be annually adjusted by changes in economy-wide productivity. The year that the productivity adjustment is effective varies by payment system. Specifically, section 3401 of the Affordable Care Act requires that in CY 2011 (and in subsequent years) update factors under the ambulatory surgical center (ASC) payment system, the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS) and the DMEPOS fee schedule be adjusted by changes in economy-wide productivity. Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to add clause (xi)(II) which sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Historical published data on the measure of MFP is available on the Bureau of Labor Statistics' (BLS) Web site at *http://www.bls.gov/mfp.*

As stated in the CY 2011 PFS final rule with comment period (75 FR 73394), the projection of MFP is currently produced by IHS Global Insight, Inc. (IGI). The methodology for calculating MFP for the ASC payment system, and the Ambulance, CLFS, and DMEPOS fee schedules was finalized in

the CY 2011 PFS final rule with comment period (75 FR 73394 through 73399). As described in the CY 2011 PFS final rule with comment period, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from the IGI U.S. macro-economic models. For CY 2012, we are proposing to revise the IGI series used to proxy the labor index used in the MFP forecast calculation from man-hours in private nonfarm establishments (billions of hours—annual rate) to hours of all persons in private nonfarm establishments, (2005 = 100.00), adjusted for labor composition effects. We are proposing this revision after further analysis showed that the proposed series is a more suitable proxy for the BLS Private nonfarm business sector labor input series since it accounts for the changes in skill-mix of the workforce over time (referred to above as labor composition effects). The BLS labor input series includes labor composition effects. We are proposing no additional changes to the IGI MFP forecast methodology or its application to the CPI–U update factors for the ASC payment system, and the Ambulance, CLFS, and DMEPOS fee schedules.

D. Section 105: 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), as 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) and section 3104 of the Affordable Care Act (Pub. L. 111–148), is amended by section 105 of the Medicare and Medicaid Extenders Act of 2010 (MMEA) (Pub. L. 111–309) to continue payment to independent laboratories for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital through CY 2011. The technical component (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 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 through 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 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. Subsequent to publication of the CY 2011 PFS final rule with comment period, section 105 of the MMEA extended the payment through CY 2011.

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

Consistent with this statutory change, we are proposing to revise § 415.130(d) to specify that for services furnished after December 31, 2011, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient. We would implement this provision effective for TC services furnished on or after January 1, 2012.

E. Section 4103 of the Affordable Care Act: Medicare Coverage and Payment of the Annual Wellness Visit Providing a Personalized Prevention Plan Covered Under Medicare Part B

1. Incorporation of a Health Risk Assessment as Part of the Annual Wellness Visit

a. Background and Statutory Authority—Medicare Part B Coverage of an Annual Wellness Visit Providing Personalized Prevention Plan Services

Preventive care and beneficiary wellness are important to the Medicare program and have become an increasing focus. In section 4103 of the Affordable Care Act, the Congress expanded Medicare coverage under Part B to include an annual wellness visit providing personalized prevention plan services (hereinafter referred to as the annual wellness visit or AWV). The AWV is described more fully in section 1861(hhh) of the Act, and coverage was effective for services furnished on or after January 1, 2011. Regulations for Medicare coverage of the AWV are

established at 42 CFR 410.15. The AWV may be performed by a physician, nonphysician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist), or a medical professional (including a health educator, a registered dietitian, or a nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician. In summary, for CY 2011, the first AWV includes—

- Establishment of an individual's medical and family history;
- Establishment of a list of current medical providers and suppliers involved in providing medical care to the individual;
- Measurement of an individual's height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history;
- Detection of any cognitive impairment that the individual may have;
- Review of the individual's potential (risk factors) for depression;
- Review of the individual's functional ability and level of safety;
- Establishment of a written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered by Medicare;
- Establishment of a list of risk factors for which primary, secondary or tertiary interventions are recommended or underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination, and a list of treatment options and their associated risks and benefits;
- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management; and
- Any other element determined appropriate through the national coverage determination process (NCD).

In summary, for CY 2011, subsequent AWVs include—

- An update of the individual's medical and family history;
- An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual;
- Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history;
- Detection of any cognitive impairment that the individual may have;
- An update to the written screening schedule for the individual;
- An update to the list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual;
- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services;
- Any other element determined appropriate through the NCD process.

The AWV is specifically designed as a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar with since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act.

Section 1861(hhh)(1)(A) of the Act specifies that a personalized prevention plan for an individual includes a health risk assessment (HRA) that meets the guidelines established by the Secretary. In general, an HRA is an evaluation tool designed to provide a systematic approach to obtaining accurate information about the patient's health status, injury risks, modifiable risk factors, and urgent health needs. This evaluation tool is completed prior to, or as part of, an AWV. The information from the HRA is reflected in the personalized prevention plan that is created for the individual.

Although the AWV was effective on January 1, 2011, section 4103 of the Affordable Care Act provided the Secretary additional time to establish guidelines for HRAs after consulting with relevant groups and entities (see section 1861 (hhh)(4)(A) of the Act). A technology assessment from the Agency for Healthcare Research and Quality (AHRQ) was commissioned to describe key features of HRAs, to examine which features were associated with successful HRAs, and to discuss the applicability of HRAs to the Medicare population. A draft of the technology assessment dated January 19, 2011 is publically available on the CMS Web site at *http://www.cms.gov/determinationprocess/downloads/id79ta.pdf.*

We collaborated with the Centers for Disease Control and Prevention (CDC), due to their in-depth knowledge of HRAs, and because the CDC was directed by section 4004(f) of the Affordable Care Act to develop guidelines for a personalized prevention plan tool. In the November 16, 2010 **Federal Register** (75 FR 70009), CDC issued a notice to solicit feedback regarding HRA guidance development. Public comments were received from numerous relevant groups and entities including: The American Academy of Family Physicians; the American Dietetic Association; the American Geriatrics Society; the American College of Cardiology; Care Continuum Alliance, physician practices; public health agencies; healthcare research groups; and the general public.

The CDC convened a public meeting in Atlanta, Georgia in February 2011 to facilitate the development of guidance for HRAs. (See the December 30, 2010 **Federal Register** (75 FR 82400)—announcement for ''Development of Health Risk Assessment Guidance, Public Forum''). This meeting allowed broad public input from stakeholders and the general public into the development of guidelines for evidence-based HRAs. The Interim Guidance for Health Risk Assessments developed by the CDC is available on the CMS Web site at *http://www.cms.gov/coverage geninfo/downloads/healthrisk assessmentsCDCfinal.pdf.* The CDC guidance resulted from a review and compilation of the current scientific evidence, the technology assessment, expert advice from those working in the field of HRA and wellness, and takes into account public feedback from the request for information and the public meeting. The CDC guidance includes questions and topics to be addressed as deemed appropriate for the beneficiary's age. Additional information regarding the CDC guidance development process is included as part of the guidance document. The CDC plans to publish ''A Framework for Patient-Centered Health Assessments, a Morbidity and Mortality Weekly Report (MMWR).'' The MMWR will include additional information applicable for the successful implementation of the HRA, such as the CDC interim guidance document, as well as information related to implementation, feedback, and follow-up that evidence suggests is critical for improving health outcomes using this process. We are interested in receiving feedback regarding the availability of

HRAs that are available for use by the general public.

b. Implementation

Consistent with section 1861(hhh) of the Act and the initial CDC guidance document, we propose to amend 42 CFR 410.15 by: (1) Adding the term ''health risk assessment'' and its definition; (2) revising the definitions of ''first annual wellness visit providing personalized prevention plan services'' and ''subsequent annual wellness visit providing personalized prevention plan services;'' and (3) incorporating the use and results of an HRA into the provision of personalized prevention plan services during the AWV. We believe that incorporation of the HRA supports a systematic approach to patient wellness and is integral to providing personalized prevention plan services. The results of the HRA will provide the foundation for and facilitate development of the personalized prevention plan. We believe that the results of the HRA will aid in developing the personalized prevention plan and, once fully implemented, will increase the efficiency of the physician's effort during the AWV.

(1) Definition of a ''Health Risk Assessment''

We propose to revise § 410.15 by adding the term ''health risk assessment'' and defining such term as an evaluation tool that meets the following requirements:

- Collects self-reported information about the beneficiary.
- Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.
- Is appropriately tailored to and takes into account the communication needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs,
- Takes no more than 20 minutes to complete.
- Addresses, at a minimum, the following topics:

++ Demographic data, including but not limited to age, gender, race, and ethnicity.

++ Self assessment of health status, frailty, and physical functioning.

++ Psychosocial risks, including but not limited to depression/life satisfaction, stress, anger, loneliness/social isolation, pain, or fatigue.

++ Behavioral risks, including but not limited to tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual practices, motor vehicle safety (seat belt use), and home safety.

++ Activities of daily living (ADLs), including but not limited to dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

++ Instrumental activities of daily living (IADLs), including but not limited to shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

The CDC guidance describes an HRA as ''a collection of health-related data a medical provider can use to evaluate the health status and the health risk of an individual. An HRA will identify health behaviors and risk factors known only to the patient (such as, smoking, physical activity and nutritional habits) for which the medical provider can provide tailored feedback in an approach to reduce the risk factors'' as well as the potential for diseases for which those risk factors are related.

The CDC guidance further explains that the ''questions/topics to be addressed in the HRA is a compilation of the current scientific evidence and are intended for Medicare beneficiaries as appropriate for their age.'' These include collection of demographic data; self assessment of health status, frailty, and physical functioning; biometric assessments obtained by the provider; psychosocial risks; and behavioral risks. The guidance document suggests, based on current evidence that the following domains specific to the greater than or equal to a 65-year-old Medicare population be included in the HRA: Memory, activities of daily living, and instrumental activities of daily living.

With regard to memory, the CDC guidance states ''that cognition assessment is not part of the HRA itself, but rather an additional aspect of the AWV * * *''. We note that the definitions of both the first and subsequent annual wellness visit include the detection of any cognitive impairment. The CDC guidance, consistent with section 1861(hhh)(4)(A) of the Act, specifies that an HRA should be made available to all Medicare beneficiaries who are eligible to receive an AWV, as defined in § 410.15; can be furnished in a number of ways, including during an encounter with a health professional or through an interactive telephonic or web-based program, while ensuring the privacy of the beneficiary; be provided in a patient's preferred language; and take no longer than 20 minutes to complete. We believe that the health professional should consider the beneficiary's needs when determining whether assistance would be needed for the beneficiary to complete the HRA. Factors a health professional may wish to consider include vision, hearing, or language limitations; the communication needs of underserved populations; persons with limited English proficiency; and persons with health literacy needs.

The completed HRA and results would be provided to the health professional as that term is defined in § 410.15(a), as a foundation for completing the elements included in the definitions of first and subsequent AWVs during the AWV encounter. The CDC guidance document explains that ''during the visit, the HRA information, and other biometrics available are utilized by the practitioner in a thought process intended to develop a prevention plan for the patient to improve health status and delay the onset of disease known to be caused by the reported behavioral risks or the patient's current health status. The practitioner can, in a shared decisionmaking process with the patient provide feedback in the form of educational messages, counseling or referrals related to changing high risk behaviors and health habits. This feedback can potentially improve health behaviors and/or alter one's risk of disease, improve chronic disease management or likelihood of premature death.'' For instance, the HRA may collect aspects of the beneficiary's medical and family history, such as history of tobacco use, that would provide a foundation for personalized health advice, and if deemed appropriate, referral for additional preventive services after completion of the AWV. We note that the standards outlined in the proposed definition of the term health risk assessment represent a minimum set of topics that need to be addressed as part of an HRA, while allowing the health professional the flexibility to evaluate additional topics, as appropriate, to provide a foundation for development of a personalized prevention plan.

(2) Proposed Changes to the Definitions of ''First Annual Wellness Visit'' and ''Subsequent Annual Wellness Visit''

In § 410.15, we adopted the components of the AWV, consistent with the statutory elements described in section 1861(hhh)(2) of the Act. The first and subsequent annual wellness visits, as defined in § 410.15(a), are meant to represent a beneficiary visit focused on prevention. Among other things, the annual wellness visit encourages beneficiaries to obtain the preventive services covered by Medicare

that are appropriate for them. First and subsequent AWVs also include elements that focus on the furnishing of personalized health advice and referral, as appropriate, to health education, preventive counseling services, programs aimed at improving self-management, and community-based lifestyle interventions.

We are proposing that the definitions of ''first annual wellness visit providing personalized prevention plan services'' and ''subsequent annual wellness visit providing personalized prevention plan services'' be revised to incorporate the use and results of an HRA. The HRA is an integral part of the provision of personalized prevention plan services, consistent with section 1861(hhh) of the Act. We propose to incorporate the HRA by revising the definitions of first and subsequent AWVs as follows:

- Specify that the AWV take into account the results of an HRA.
- Add the review (and administration, if needed) of an HRA as an element of both first and subsequent AWVs.
- Specify that the establishment of a written screening schedule for the individual, such as a checklist, includes and takes into account the HRA.

The HRA facilitates a systematic method for identifying health behaviors and risk factors known to the patient (such as: Smoking, physical activity, and nutritional habits) for which the medical provider can discuss and provide tailored feedback aimed at reducing risk factors as well as reducing the potential for developing the diseases to which they are related.

During the AWV encounter, the HRA information is utilized by the health professional in a thought process intended to develop a personalized prevention plan for the patient to improve health status and delay the onset of disease. For instance, if the information provided by the HRA indicated that the beneficiary had a current or past history of tobacco use, the health professional may deem it appropriate to perform those commonly used aspects of a clinical evaluation (for instance, listening to (auscultation) the heart and lungs) in order to provide the appropriate personalized health advice and referrals for additional preventive services such as tobacco cessation counseling.

The CDC guidance document provides a list of questions/topics to be addressed in an HRA, including biometric assessments of height, weight, body mass index (BMI), systolic/diastolic blood pressure, blood lipids (HDL/LDL and total cholesterol, triglycerides), and blood glucose. Additionally, the CDC guidance document suggested that the information collected via the HRA would be reconciled with biometric assessments obtained by the provider. Consistent with section 1861(hhh)(2) of the Act, the definitions for first AWV and subsequent AWVs address most of the biometric assessments suggested in the CDC guidance document. We are requesting public comment on the applicability and impact of including additional elements and biometric assessments to first and subsequent AWVs, per the Secretary's authority under section 1861(hhh)(2)(G) of the Act.

We believe that the incorporation of the HRA would increase the efficiency of the health professional's effort during the AWV. For instance, during the AWV encounter, the health professional furnishing the AWV would review the information reported in the HRA, which would serve as the basis for a personalized prevention plan provided during the AWV encounter. The beneficiary would leave the visit with personalized health advice, appropriate referrals, and a written individualized screening schedule, such as a check list. We would not expect that the health professional would provide only general recommendations during the AWV encounter and then mail a personalized prevention plan that incorporates an HRA to the beneficiary outside of the AWV encounter. While the AWV is a wellness visit that focuses on wellness and disease prevention, a follow-up visit to treat an identified illness may be needed to address an urgent health issue. For example, if a beneficiary is determined to have high blood pressure, a follow-up visit for further review of symptoms and evaluation and management, along with determining whether additional interventions are necessary, may be performed after the completion of the AWV as a separate service.

We are requesting public comment on the overall impact and burden of the AWV on health professional practices, including the impact that incorporation of the use of an HRA will have on health professionals and their practices. Specifically, we are seeking public comment on the following:

- The impact of use of an HRA on health professional practices;
- The burden on health professional practices of incorporating an HRA into subsequent AWVs as well as the first AWV;
- The impact of the elements included in the definitions of first and subsequent AWV.
- Modification of those AWV elements for which the Secretary has authority to determine appropriateness.

We are also proposing changes to the definition of the term ''subsequent annual wellness visit providing personalized prevention plan services'' to clarify that the health professional should furnish personalized prevention plan services and updated information if there have been changes since the beneficiary's last AWV, whether that was a first AWV or a subsequent AWV. In the CY 2011 PFS final rule with comment period, we stated in the definition of ''subsequent annual wellness visit providing personalized prevention plan services'' that certain elements should be updated based on information developed during the first AWV (for example, lists of risk factors and screening schedules). Since all AWVs that follow the first AWV are considered subsequent AWVs, the health professional should update elements that were developed during the previous AWV if there have been changes. The proposed changes to the definition of the term ''subsequent annual wellness visit providing personalized prevention plan services'' are as follows:

- We propose that newly redesignated paragraph (iii) state ''an update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.''
- We propose that newly redesignated paragraph (vi)(B), state ''the list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.''

2. The Addition of a Health Risk Assessment as a Required Element for the Annual Wellness Visit Beginning in 2012

Section 4103 of the Affordable Care Act created a new benefit for an ''annual wellness visit'' (AWV) providing personalized prevention plan services (PPPS). The Affordable Care Act amended section 1861(s)(2) of the Act by adding new subparagraph (FF) to provide for coverage of the AWV beginning January 1, 2011. Section 4103

of the Affordable Care Act also added new subsection (hhh) to section 1861 of the Act to define ''personalized prevention plan services'' and to specify who may furnish these services. Finally, section 4103 of the Affordable Care Act amended section 1848(j)(3) of the Act and provided for payment of AWVs under the PFS, and specifically excluded the AWV from the hospital OPPS. As discussed in the CY 2011 PFS final rule with comment period (75 FR 73401), a single Medicare payment is made when an AWV is furnished by a physician, physician assistant, nurse practitioner, or clinical nurse specialist, or by a medical professional or team of medical professionals, under the direct supervision of a physician.

In the CY 2011 PFS final rule with comment period (75 FR 73409), we established two HCPCS G-codes for reporting the AWV beginning in CY 2011: G0438 (Annual wellness visit; includes a personalized prevention plan of service (PPPS), first visit) and G0439 (Annual wellness visit; includes a personalized prevention plan of service (PPPS), subsequent visit).

A beneficiary is eligible for only one first AWV (HCPCS code G0438) covered by Medicare that must include all of the required elements that we adopted in our final policy for the CY 2011 PFS final rule with comment period (75 FR 73399). All subsequent AWVs (HCPCS code G0439) include the required elements for those visits as finalized in the CY 2011 PFS final rule with comment period (75 FR 73399). All AWVs other than the beneficiary's first AWV shall be reported as subsequent visits, even if a different practitioner furnished the subsequent AWV. We expect there to be continuity and communication among the practitioners caring for beneficiaries over time with respect to AWVs, and this would include the case where a different practitioner furnishing a subsequent AWV would update the information in the patient's medical record based on the patient's interval history since the previous AWV.

As we stated in the CY 2011 PFS final rule with comment period (75 FR 73409), we believe that the first AWV described by HCPCS code G0438 is similar to the IPPE that is currently reported with HCPCS code G0402 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment). We note that in the CY 2010 PFS final rule with comment period discussion of payment for the IPPE (74 FR 61767), we stated that in the context of physician work and intensity, HCPCS code G0402 was most equivalent to CPT code 99204 (Level 4 new patient office or other outpatient visit). In addition, in the CY 2011 PFS final rule with comment period (75 FR 73410), we indicated that subsequent AWV's described by HCPCS code G0439 are most similar, from the perspectives of physician work and PE, to CPT code 99214 (Level 4 established patient office or other outpatient visit). Therefore, we valued HCPCS codes G0438 and G0439 for payment under the PFS using a crosswalk methodology for the work RVUs and direct PE inputs from the level 4 new and established patient office or other outpatient visit CPT codes, respectively.

a. Payment for AWV services with the inclusion of an HRA element

In the CY 2011 PFS final rule with comment period (75 FR 73411), we stated ''that when the HRA is incorporated in the AWV, we will reevaluate the values for HCPCS codes G0438 and G0439''. As discussed in the CY 2011 PFS final rule with comment period, the services described by CPT codes 99204 and 99214 already include 'preventive assessment' forms. For CY 2012, we believe that the current payment crosswalk for HCPCS codes G0438 and G0439 continue to be most accurately equivalent to a level 4 E/M new or established patient visit; and therefore, we are proposing to continue to crosswalk HCPCS codes G0438 and G0439 to CPT codes 99204 and 99214, respectively.

F. Quality Reporting Initiatives

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

a. Program Background and Statutory Authority

The Physician Quality Reporting System is a quality reporting program that provides incentive payments and payment adjustments to identified eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. The Physician Quality Reporting System was initially implemented in 2007 as a result of section 101 of Division B of the Tax Relief and Health Care Act of 2006. The Physician Quality Reporting System was extended and further enhanced as a result of the Medicare Improvements for Patients and Providers Act of 2009 (MIPPA), which was enacted on July 15, 2008, and the Affordable Care Act, which was enacted on March 23, 2010.

Changes to the Physician Quality Reporting System as a result of these laws, as well as information about the Physician Quality Reporting System in 2007, 2008, 2009, 2010, and 2011 are discussed in detail in the CY 2008 PFS proposed and final rules (72 FR 38196 through 38204 and 72 FR 66336 through 66353, respectively), CY 2009 PFS proposed and final rules (73 FR 38558 through 38575 and 73 FR 69817 through 69847, respectively), CY 2010 PFS proposed and final rules (74 FR 33559 through 33600 and 74 FR 61788 through 61861, respectively), and CY 2011 PFS proposed and final rules (75 FR 73487 through 73552). Further detailed information, about the Physician Quality Reporting System, related laws, and help desk resources, is available on the CMS Web site at *http://www.cms.gov/PQRS.*

In the CY 2011 PFS final rule (75 FR 73618), we established 42 CFR 414.90 governing the Physician Quality Reporting System.

b. Methods of Participation

There are two ways an eligible professional may participate in the Physician Quality Reporting System: (1) As an individual eligible professional or (2) as part of a group practice under the Physician Quality Reporting System group practice reporting option (GPRO). The details of each proposed method of participation are described in this section.

(1) Individual Eligible Professionals

As defined at 42 CFR 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 Physician Quality Reporting CMS Web site at: *http://www.cms.gov/PQRS/03_How_To_Get_Started.asp#TopOfPage.*

(2) Group Practices

(A) Background and Authority

As required by section 1848(m)(3)(C)(i) of the Act, we established and have had in place since January 1, 2010, a process under which eligible professionals in a group practice are treated as satisfactorily submitting data on quality measures under the Physician Quality Reporting System if, in lieu of reporting measures under the Physician Quality Reporting System, the group practice reports measures

determined appropriate by the Secretary, for example measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time specified by the Secretary. Section 1848(m)(3)(C)(ii) of the Act requires that this process provide for the use of a statistical sampling model to submit data on measures, for example the model used under the Medicare Physician Group Practice (PGP) demonstration project under section 1866A of the Act. We established a group practice reporting option (GPRO) for the Physician Quality Reporting System under 42 CFR 414.90(g).

(B) Proposed Definition of Group Practice

Under 42 CFR 414.90(b), a ''group practice'' means ''a single Tax Identification Number (TIN) with two or more eligible professionals, as identified by their individual National Provider Number (NPI), who have reassigned their Medicare billing rights to the TIN''. We propose to change the definition of ''group practice'' under 42 CFR 414.90(b). Specifically, we propose that under the Physician Quality Reporting System, a ''group practice'' would consist of a physician group practice, as defined by a TIN, with 25 or more individual eligible professionals (or, as identified by NPIs) who have reassigned their billing rights to the TIN. This proposed definition of group practice is different from the definition of group practice that was applicable for the 2011 Physician Quality Reporting System, which defined a group practice as two or more eligible professionals.

For the 2010 Physician Quality Reporting System, our definition of ''group practice'' was limited to practices with 200 or more eligible professionals because our intent was to model the Physician Quality Reporting System GPRO after a quality reporting program that group practices may already be familiar with—the Physician Group Practice (PGP) demonstration. Since participation in the PGP demonstration was limited to large group practices, we wanted to initially limit participation in the Physician Quality Reporting System GPRO to similar large group practices. In 2011, we expanded this definition to include practices with 2–199 eligible professionals because we developed a second reporting option (GPRO II) specifically for smaller group practices that was based largely on the Physician Quality Reporting System reporting options for individual eligible professionals. We have since observed that many of these smaller group practices that self-nominated to participate in GPRO II for 2011 subsequently elected to opt out of participation in the GPRO II for 2011 so that members of the group practices can participate in the Physician Quality Reporting System individually instead. Out of 107 total groups that self-nominated for GPRO II, only 25 group practices comprised of 2–10 eligible professionals and 15 group practices comprised of 11–25 eligible professionals are still participating in GPRO II for 2011 at this time.

Since the GPRO II seems to be a less attractive reporting option than GPRO I, we are proposing in section IV.F.1.b.2 of this proposed rule to consolidate GPRO I and II into a single GPRO. However, since our experience with using the GPRO submission web interface under the Physician Quality Reporting System has been limited to larger practices or practices participating in demonstration projects, we hesitate to expand what we referred to as GPRO I to all group practices until we gain some experience with smaller practices on a larger scale. For example, we believe that participation under the Physician Quality Reporting System GPRO is a more effective method of participation for larger as opposed to smaller group practices. As described in section IV.F.1.e.6 of this proposed rule, a group practice must take extra steps to participate in the Physician Quality Reporting System GPRO, for example reporting on more measures overall than is required for individual eligible professionals. In contrast, members of a group practice who choose to participate in the Physician Quality Reporting System as individual eligible professionals could satisfactorily report by reporting as few as 3 measures. We believe the additional reporting burden associated with participating under the Physician Quality Reporting System GPRO may make the GPRO less attractive for smaller practices. For these reasons, we propose to change the definition of ''group practice'' at 42 CFR 414.90(b) to groups with 25 or more eligible professionals.

Our proposal to change the definition of group practice would not preclude individual eligible professionals in group practices of less than 25 eligible professionals from participating in the Physician Quality Reporting System, since members of these group practices may still participate as individual eligible professionals. We believe that smaller group practices are more closely akin to individual eligible professionals with respect to participation under the Physician Quality Reporting System. We request comments on the proposed change to the definition of ''group practice'' under 42 CFR 414.90(b) under the Physician Quality Reporting System and also, whether we should retain the existing definition under the regulation despite our proposal to retain only the GPRO I for 2012.

We recognize that a group's size can fluctuate throughout the year as professionals move from practice to practice. We allow for fluctuation of the group practice's size throughout the reporting period. However, the group practice's size after the group practice's participation is approved by CMS must continue to meet the definition of a group practice as proposed in 42 CFR 414.90(b) for the entire reporting period.

We also note that under 42 CFR 414.90(g)(1), a group practice of any size (including solo practitioners) or comprised of multiple TINs participating in a Medicare approved demonstration project of other programs would also be deemed to be participating in the Physician Quality Reporting System GPRO. For example, the PGP demonstration, as well as the Medicare Shared Savings Program (governing accountable care organizations (ACOs)), Pioneer ACO, and EHR demonstrations have incorporated or proposed to incorporate aspects of the Physician Quality Reporting System reporting requirements and incentives under those respective programs.

Our intention to recognize (deem) group practices participating in such other programs or demonstration projects as having participated in the Physician Quality Reporting System was to ensure that such groups would not be barred from participating in the group practice reporting option under the eRx Incentive program, since we previously required that group practices interested in participating in the eRx Incentive Program also participate in the Physician Quality Reporting System GPRO. We are not proposing to change the eligibility for group practices, including those participating in the programs mentioned above, to participate in the eRx Incentive program. As discussed in the proposed changes to the eRx Incentive Program in section IV.F.1.e.2 later in this proposed rule, however, we are proposing that a group practice must self-nominate to participate under the eRx Incentive Program's group practice reporting option. In addition, we are proposing to make a technical change to 42 CFR 414.90(g)(1) to eliminate the reference to group practices in demonstrations that are deemed to have participated in the Physician Quality Reporting System. We believe that this language is unnecessary given the regulation at 42 CFR

414.92(b). In addition, we believe that retaining the reference at 42 CFR 414.90(g)(1) may cause confusion with regard to participation under the Physician Quality Reporting System or inappropriately suggest that duplicate Physician Quality Reporting System incentive payments are available to group practices under both the Physician Quality Reporting System and the other types of programs mentioned previously. We also propose to make a technical change to 42 CFR 414.92(b) to more broadly address group practices in other types of programs that incorporate Physician Quality Reporting System reporting requirements and incentives, so that the regulation does not solely reference demonstrations. We seek comments on these proposed technical changes to the regulations.

Since the introduction of the Physician Quality Reporting System GPRO in 2010, eligible professionals within a group practice were required to assign their billing rights to a single TIN. For 2012, as stated previously, we are proposing to retain this requirement. However, in an effort to align the Physician Quality Reporting System with other CMS quality reporting group programs, we considered amending the definition of ''group practice'' to allow participation in the Physician Quality Reporting System GPRO by groups with 25 or more individual eligible professionals (or, as identified by NPIs) who practice using multiple TINs. We believe that changing the definition of group practice in the Physician Quality Reporting System for future program years to align with other quality reporting group programs may be beneficial to providers who wish to participate in multiple CMS quality reporting programs that apply to group practices. Although we are not proposing to do so at this time, we invite public comment on possibly expanding the definition of group practice to be comprised of multiple TINs in future years of the program.

We believe that to the extent we changed the definition of group practice in future years to allow for participation by group practices that use multiple TINs, it would require us to create additional parameters related to the relationship between the various TINs. As such, we also invite public comment on parameters that should be set to ensure that these multiple TINs represent a single integrated practice, such as but not limited to:

- Must eligible professionals in a group practice share certain common characteristics in order to be eligible for participation under the Physician Quality Reporting System GPRO, such as geographic location or specialty?
- Should there be a limit to how many TINs may be comprised in a single group practice?

We invite public comment on parameters that may be set should we decide to amend the definition of group practice to include multiple TINs in future program years.

(C) Proposed Process for Physician Group Practices to Participate as Group Practices

In order to participate in the Physician Quality Reporting System GPRO for 2012 and subsequent years, we propose to require group practices to complete a self-nomination process and to meet certain technical and other requirements described later in this section in greater detail. As in prior years, we are proposing to require these self-nomination and additional process requirements so that we may identify which group practices are interested in participating in the Physician Quality Reporting System as a GPRO as well as to ensure that group practices participating in the GPRO understand the process for satisfactorily reporting Physician Quality Reporting System quality measures under the GPRO method of reporting.

We propose to require that group practices interested in participating in the Physician Quality Reporting System GPRO for the first time submit a self-nomination statement for the respective year the group practice wishes to participate as a Physician Quality Reporting System GPRO via a Web-based tool that includes the group practice's TIN(s) and name of the group practice, the name and e-mail address of a single point of contact for handling administrative issues, as well as the name and e-mail address of a single point of contact for technical support purposes. A group practice that submits an incomplete self-nomination statement, such as a valid e-mail address is not provided, would not be considered for inclusion in the Physician Quality Reporting System GPRO. We would notify any group practice that submits an incomplete self-nomination statement.

If it is not operationally feasible for us to collect self-nomination statements via a Web-based tool for 2012, we propose to require that group practices interested in participation in the Physician Quality Reporting System GPRO submit a self-nomination statement via a letter accompanied by an electronic file submitted in a format specified by us (such as a Microsoft Excel file) that includes the group practice's TIN(s) and name of the group practice, the name and e-mail address of a single point of contact for handling administrative issues, as well as the name and e-mail address of a single point of contact for technical support purposes. Under this proposed submission mechanism, a group practice that submits an incomplete self-nomination statement (such as, a valid e-mail address is not provided), would not be considered for inclusion in the 2012 Physician Quality Reporting System GPRO.

For the Physician Quality Reporting System GPRO, we propose that the self-nomination statement must also indicate the group practice's compliance with the following requirements:

- Agree to attend and participate in all mandatory GPRO training sessions.
- Is an established Medicare provider that has billed Medicare Part B on or after January 1 and prior to October 29 of the year prior to the reporting period for the respective year. For example, for purposes of participating in the 2012 Physician Quality Reporting System GPRO, the group practice must have billed Medicare Part B on or after January 1, 2011 and prior to October 29, 2011.
- Agree to have the results on the performance of their Physician Quality Reporting System measures publicly posted on the Physician Compare Web site.
- Obtain and/or have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit Medicare clinical quality data to a CMS clinical data warehouse.
- Provide CMS access (upon request for validation purposes) to review the Medicare beneficiary data on which Physician Quality Reporting System GPRO submissions are founded or provide to CMS a copy of the actual data (upon request).

Furthermore, to ensure that accurate data is being reported, we reserve the right to validate the data submitted by GPROs.

We propose that, for 2012 and future years, a group practice that wishes to participate in both the Physician Quality Reporting System and eRx GPRO (see the eRx Incentive Program's section IV.F.2.(b).(2).(B). of this proposed rule) must indicate its desire to participate in both programs in its self-nomination statement.

In 2012, the GPRO is interested in testing the extraction of EHR data submitted by group practices through the GPRO Web interface. We propose that those group practices wishing to participate in this test must state their

interest to participate in the group practice's self-nomination letter.

We further propose that group practices that wish to self-nominate must do so by January 31 of the calendar year in which the group practice wishes to participate in the Physician Quality Reporting System GPRO. For example, in order to participate in the GPRO for the 2012 Physician Quality Reporting System, the group practice would need to self-nominate by January 31, 2012. Upon receipt of the self-nomination statements, we would assess whether the participation requirements for the respective reporting period were met by each group practice using Medicare claims data from the year prior to the respective reporting period. We would not preclude a group practice from participating in the GPRO if we discover, from analysis of the Medicare claims data, that there are some eligible professionals (identified by NPIs) that are not established Medicare providers (that is, have not billed Medicare Part B on or after January 1 and prior to or on October 29 of the year prior to the respective reporting period) as long as the group has at least the minimum proposed number (that is, 25) of established Medicare providers required to participate in the Physician Quality Reporting System as a group practice. Eligible professionals, as classified by their NPIs, who do not submit Medicare Part B claims for PFS covered professional services during the reporting period, however, would not be included in our incentive payment calculations.

Furthermore, we propose to allow group practices who have previously participated in the Physician Quality Reporting System GPRO to automatically be qualified to participate in the GPRO in 2012 and future program years. For example, group practices that were selected to participate in the 2011 Physician Quality Reporting System GPRO I or GPRO II (provided the group practice is still comprised of at least 25 eligible professionals) would automatically be qualified to participate in the 2012 Physician Quality Reporting System GPRO and would not need to complete the 2012 Physician Quality Reporting System GPRO qualification process. These practices would, however, need to notify CMS in writing of their desire to continue participation in the Physician Quality Reporting System GPRO for the respective program year.

We recognize that, for various reasons, there potentially could be a discrepancy between the number of eligible professionals (that is, NPIs) submitted by the practice during the self-nomination process and the number of eligible professionals billing Medicare under the practice's TIN as people move in and out of practices. Therefore, if we find more NPIs in the Medicare claims than the number of NPIs submitted by the practice during the self-nomination process and this would result in the practice being subject to different criteria for satisfactory reporting, we propose to notify the practice of this finding as part of the self-nomination process. At this point, the practice would have the option of either agreeing to be subject to the different criteria for satisfactory reporting or opting out of participation in the Physician Quality Reporting System GPRO to enable the members of their practice to participate in the Physician Quality Reporting System as individual eligible professionals.

We invite public comment on our proposals regarding the process for physician group practices to participate in the Physician Quality Reporting System GPRO.

c. Proposed Reporting Period

Since the implementation of the Physician Quality Reporting System in 2007, depending on an eligible professional's chosen reporting mechanism, we have offered up to two different reporting periods for satisfactorily reporting Physician Quality Reporting System quality measures: A 12-month reporting period (from January 1 through December 31 of the respective program year) and a 6-month reporting period (from July 1 through December 31 of the respective program year). Section 1848(m)(5)(F) of the Act requires CMS to provide alternative reporting periods and criteria for measures groups and registry reporting. To comply with this provision, for 2012 and subsequent years, CMS is proposing to retain the 6-month reporting period option for the reporting of Physician Quality Reporting System measures groups via registry.

In addition, for 2012 and subsequent years, we propose to modify 42 CFR 414.90(f)(1) to specify a 12-month reporting period (that is, January 1 through December 31 of the respective program year), consistent with section 1848(m)(6)(C)(i)(II) of the Act, for the satisfactory reporting of Physician Quality Reporting System quality measures for claims, registry, and EHR-Based reporting. Additionally, we propose to modify 42 CFR 414.90(g)(1) to specify a 12-month reporting period (that is, January 1 through December 31 of the respective program year) for the Physician Quality Reporting System GPRO. We understand that in proposing these modifications to 42 CFR 414.90, we are proposing to eliminate the 6-month reporting period for claims and registry previously available under the Physician Quality Reporting System (with the exception of reporting measures groups via registry). Although we are not proposing a 6-month reporting period for claims and registry reporting (for reporting individual measures via registry), we note that the 12-month reporting period aligns with other CMS quality reporting programs. In addition, the elimination of the 6-month reporting period for claims and registry reporting (for reporting individual measures via registry) will align the reporting periods of these mechanisms with the EHR reporting mechanism. We further believe that the elimination of the 6-month reporting period for claims and registry reporting (for reporting individual measures via registry) will help to streamline and simplify the reporting requirements for the Physician Quality Reporting System without substantial burden to eligible professionals who may still satisfactorily report using the 12-month reporting period.

d. Proposed Reporting Mechanisms—Individual Eligible Professionals

For the purpose of reporting quality measures under the Physician Quality Reporting System, we propose to retain the claims-based, registry-based, and EHR-Based reporting mechanism for 2012 and beyond. Accordingly, we propose to modify 42 CFR 414.9(f) to reflect this proposal. We are proposing to retain these reporting mechanisms in order to provide eligible professionals with multiple mechanisms from which to satisfactorily report Physician Quality Reporting System quality measures. We hope that offering multiple reporting mechanisms will aid in encouraging participation in the Physician Quality Reporting System.

As in previous years, the individual quality measures or measures groups an eligible professional selects will dictate the applicable reporting mechanism(s). In addition, while eligible professionals can attempt to qualify for a Physician Quality Reporting System incentive under multiple reporting mechanisms, the eligible professional must satisfy the criteria for satisfactory reporting proposed for the respective program year, with respect to a single reporting mechanism to qualify for an incentive. We further propose that we would not combine data submitted via multiple reporting mechanisms to determine incentive eligibility. We invite public comment concerning the general, proposed reporting mechanisms for the

Physician Quality Reporting System for 2012 and beyond.

(1) Claims-Based Reporting

As we noted previously, we propose to retain the claims-based reporting mechanism for the Physician Quality Reporting System for 2012 and beyond. For eligible professionals who choose to participate in the Physician Quality Reporting System by submitting data on individual quality measures or measures groups through the claims-based reporting mechanism, we propose that the eligible professional be required to submit the appropriate Physician Quality Reporting System quality data codes (QDCs) on the professionals' Medicare Part B claims. QDCs for the eligible professional's selected individual Physician Quality Reporting System quality measures or measures group 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 2 months after the end of the reporting period, to be included in the program year's Physician Quality Reporting System analysis. For example, all claims for services furnished for the 2012 Physician Quality Reporting System would need to be processed by no later than 2 months after the end of the reporting period for the 2012 Physician Quality Reporting System, that is, processed by February 28, 2013 for the reporting period that ends December 31, 2012. We invite public comment on our proposed requirements for eligible professionals who choose the claims-based reporting mechanism for 2012 and beyond.

(2) Registry-Based Reporting

(A) Proposed Requirements for the Registry-Based Reporting Mechanism—Individual Eligible Professionals

As stated previously, we propose to retain the registry-based reporting mechanism via a qualified registry (as defined in section (2)(B) of this section) for the Physician Quality Reporting System for 2012 and beyond. With regard to specific requirements for registry-based reporting for individual eligible professional reporters under the Physician Quality Reporting System, we propose that in order to report quality data on the Physician Quality Reporting System individual quality measures or measures groups for the respective program year through a qualified registry, an eligible professional or group practice must enter into and maintain an appropriate legal arrangement with a qualified Physician Quality Reporting System registry. Such arrangements would provide for the registry's receipt of patient-specific data from the eligible professional and the registry's disclosure of quality measures results and numerator and denominator data on Physician Quality Reporting System quality measures or measures groups on behalf of the eligible professional to CMS. Thus, the registry would act as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) Business Associate and agent of the eligible professional. Such agents are referred to as ''data submission vendors.'' The ''data submission vendors'' would have the requisite legal authority to provide clinical quality measures results and numerator and denominator data on individual quality measures or measures groups on behalf of the eligible professional for the Physician Quality Reporting System.

We propose that the registry, acting as a data submission vendor, would submit CMS-defined registry-derived measures information to our designated database for the Physician Quality Reporting System, using a CMS-specified record layout, which would be provided to the registry by CMS. Similarly, we propose that eligible professionals choosing to participate in the Physician Quality Reporting System through the registry-based reporting mechanism for the respective program year must select a qualified Physician Quality Reporting System registry and submit information on Physician Quality Reporting System individual quality measures or measures groups to the selected registry in the form and manner and by the deadline specified by the registry.

We propose to post a list of qualified registries for the Physician Quality Reporting System for the respective program year on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/pqrs,* which would include the registry name, contact information, the measures and/or measures group (if qualified) for which the registry is qualified and intends to report for the respective program year, and information regarding the cost of the registry to eligible professionals. However, we do not anticipate making this list available prior to the start of the respective program year. That is, we do not anticipate making the list of qualified registries for the 2012 Physician Quality Reporting System available prior to the start of the 2012 program year. We propose to post the names of the Physician Quality Reporting System qualified registries for the respective reporting period in the following 3 phases based on: (1) The registry's success in submitting Physician Quality Reporting System quality measures results and numerator and denominator data on the quality measures in a prior Physician Quality Reporting System program year (2008, 2009, 2010, 2011, etc.); (2) the registry's submission of a letter indicating their continued interest in being a Physician Quality Reporting System registry by October 31 of the year prior to the program year (that is, by October 31, 2011 for the 2012 program year); and (3) the registry's compliance with the Physician Quality Reporting System registry requirements for the respective program year as indicated by CMS' registry vetting process. The listing of a qualified registry will depend on which of the 3 proposed phases is most applicable to the registry. The manner in which we post the list of qualified registries is based on prior experience with participation in the Physician Quality Reporting System as a registry vendor.

(B) 2012 Proposed Qualification Requirements for Registries

Although we are proposing to establish the registry-based reporting mechanism as a way to report Physician Quality Reporting System quality measures for 2012 and beyond, we propose that the following proposed qualification requirements only apply for the 2012 program year. For the Physician Quality Reporting System in 2012, as in prior program years, we propose to require a self-nomination process for registries wishing to submit Physician Quality Reporting System quality measures or measures groups on behalf of eligible professionals for services furnished during the applicable reporting periods in 2012. This qualification process allows us to ensure that registries are fully informed of the Physician Quality Reporting System reporting process and to ensure the registry is qualified, thereby improving the likelihood of accurate reporting.

We note that third party intermediaries may participate in various capacities under the Physician Quality Reporting System. In addition, in an effort to encourage the electronic submission of quality measures data from eligible professionals' EHRs, we are proposing EHR-Based reporting, as discussed later in this section. As a result, we believe it is important to distinguish entities that collect their data from an EHR from those entities that collect their data from other sources. As such, as discussed here and below, we propose, the following two

categories of third party intermediaries that would be able to submit Physician Quality Reporting System measures data on behalf of eligible professional: (1) A registry, as defined at 42 CFR 414.90(b), which would be any data submission vendor submitting data from a source other than an EHR on behalf of eligible professionals that meets the proposed registry qualification requirements later in this section; and (2) EHR data submission vendors, which would be a data submission vendor that obtains its data from an eligible professional's EHR and that meets the 2012 EHR qualification requirements. However, for operational reasons, we may reserve the right to limit such entities to a single role such that the entity would need to decide whether it wants to serve as a registry or EHR data submission vendor but not both. We note that a registry could serve as an ''EHR data submission vendor'' to the extent that it obtains data from an eligible professional's EHR, but would need to meet the proposed 2012 EHR qualification requirements. To be considered a qualified registry for purposes of serving as a registry under the program and submitting individual quality measures on behalf of eligible professionals who choose the registry reporting mechanism for 2012, we propose that both registries new to the Physician Quality Reporting System and those previously qualified must:

- Be in existence as of January 1, 2012.
- Have at least 25 participants by January 1, 2012.
- Provide at least 1 feedback report, based on the data submitted to them for the 2012 Physician Quality Reporting System incentive reporting period, and if technically feasible, provide at least 2 feedback reports throughout the year to participating eligible professionals. Although it is not a requirement that registries provide interim feedback reports, we believe it is in the stakeholder's interest to require early registry collection of data for purposes of providing a feedback report to eligible professionals before the end of the 2012 Physician Quality Reporting System incentive reporting period to determine what steps, if any, an eligible professional should take to meet the criteria for satisfactory reporting.
- For purposes of distributing feedback reports to eligible professionals, collect an eligible professional's e-mail addresses and have documentation from the eligible professional authorizing the release of his or her e-mail address.
- Not be owned and managed by an individual locally-owned single-specialty group (in other words, single-specialty practices with only 1 practice location or solo practitioner practices would be prohibited from self-nominating to become a qualified Physician Quality Reporting System registry).
- Participate in ongoing 2012 Physician Quality Reporting System mandatory support conference calls hosted by CMS (approximately 1 call per month), including an in-person registry kick-off meeting to be held at CMS headquarters in Baltimore, MD. Registries that miss more than one meeting would be precluded from submitting Physician Quality Reporting System data for the reporting year (2012).
- Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures, which is the minimum amount of measures on which an eligible professional is required to report, in the 2012 Physician Quality Reporting System (according to the posted 2012 Physician Quality Reporting System Measure Specifications);
- Be able to calculate and submit measure-level reporting rates 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 TIN/NPI reports 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.
- Provide the name of the registry.
- Provide the reporting period start date the registry will cover.
- Provide the reporting period end date the registry will cover.
- Provide the measure numbers for the Physician Quality Reporting System quality measures on which the registry is reporting.
- Provide the measure title for the Physician Quality Reporting System quality measures on which the registry is reporting.
- Report the number of eligible instances (reporting denominator).
- Report the number of instances a quality service is performed (reporting 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 (eligible professional receives credit for reporting, not for performance), meaning the quality action was not performed for no valid reason as defined by the measure specification.
- Be able to transmit this data 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 approved method, such as use of appropriate NwHIN (Nationwide Health Information Network) specifications, if technically feasible.
- Submit an acceptable ''validation strategy'' to CMS by March 31, 2012. A validation strategy ascertains whether eligible professionals have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure, which, as described in section (e)(2) of this section, is the minimum percentage of patients on which an eligible professional must report on any 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, 2013 for the 2012 reporting year's data.
- 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, 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 who wish to participate in the Physician Quality Reporting System.
- 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 Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the registry to submit Physician Quality Reporting

System quality measures data to the registry and must meet any applicable laws, regulations, and contractual business associate agreements.

• Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which 2012 Physician Quality Reporting System registry-based submissions are founded or provide to CMS a copy of the actual data (upon request).

• 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 Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS would provide registries a standard set of logic to calculate each measure and/or measures group they intend to report in 2012.

• Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the data submission vendor intends to calculate. The registries would 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.

• Provide the individual data elements used to calculate the measures upon request by CMS under its health oversight authority, if aggregated data submission is still the selected method of data collection. Registries that are subject to validation will be asked to send discrete Medicare beneficiary data elements for a measure (determined by CMS) in the required data format for us to recalculate the registries' reported results. Validation would be conducted for several measures at a randomly selected sample of registries in order to validate their data submissions.

• Provide CMS with beneficiary-level data provided to the registry by the eligible professional in the CMS-approved format, upon request by CMS. CMS intends to use the data to calculate the eligible professional's measure results (that is, reporting and performance rates).

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 2012 Physician Quality Reporting System measures groups, we propose that both registries new to the Physician Quality Reporting System and those previously qualified must:

• 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 2012 reporting period.

• Agree that the registry's data may be inspected or a copy requested by CMS and provided to CMS under our oversight authority.

• Be able to report consistent with the proposed reporting criteria requirements, as specified in section (e)(2) of this section.

We intend to post the final 2012 Physician Quality Reporting System registry requirements on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/pqrs* by November 15, 2011 or shortly thereafter. We anticipate that new registries that wish to self-nominate for 2012 would be required to do so by January 31, 2012.

We propose that registries that were ''qualified'' for 2011 and wish to continue to participate in 2012 will not need to be ''re-qualified'' for 2012, but instead would only be required to demonstrate that they can meet the new 2012 data submission requirements. For technical reasons, however, we do not expect to be able to complete this vetting process for the new 2012 data submission requirements until mid-2012. Therefore, for 2012, we may not be able to post the names of registries that are qualified for the 2012 Physician Quality Reporting System until we have determined the previously qualified registries that wish to be qualified for the 2012 Physician Quality Reporting System are in compliance with the new registry requirements.

We propose that registries ''qualified'' for 2011, who are successful in submitting 2011 Physician Quality Reporting System data, and wish to continue to participate in 2012 would need to indicate their desire to continue participation for 2012 by submitting a self-nomination statement via a web-based tool to CMS indicating their continued interest in being a Physician Quality Reporting System registry for 2012 and their compliance with the 2012 Physician Quality Reporting System registry requirements by no later than October 31, 2011. Additionally, registries that were qualified but unsuccessful in submitting 2011 Physician Quality Reporting System data (that is, fail to submit 2011 Physician Quality Reporting System data per the 2011 Physician Quality Reporting System registry requirements) would need to go through a full self-nomination vetting process for 2012.

We further propose that by March 31, 2012, registries that are unsuccessful at submitting registry data in the correct data format for 2011 would need to be able to meet the 2012 Physician Quality Reporting System registry requirements and go through the full vetting process again. This would include CMS receiving the registry's self-nomination by March 31, 2012. We propose that the aforementioned registry requirements will also apply for the purpose of a registry qualifying to submit the electronic prescribing measure for the 2012 eRx Incentive Program. We anticipate finalizing the list of 2012 Physician Quality Reporting System registries by Summer 2012.

For eligible professionals considering this reporting mechanism, we point out that even though a registry is listed as ''qualified,'' we cannot guarantee or assume responsibility for the registry's successful submission of the required Physician Quality Reporting System quality measures results or measures group results or required data elements submitted on behalf of a given eligible professional. We invite public comment on our proposed 2012 requirements for the registry-based reporting mechanism for individual eligible professional reporters.

Furthermore, in an effort to ensure that registries provide accurate reporting of Physician Quality Reporting System data, in program years after 2012, we seek to disallow previously-qualified registries from submitting data on Physician Quality Reporting System quality measures if it is found that the data registries provide are significantly inaccurate. We believe this is important because we have noticed many calculation and data submission errors in reporting from registries in past program years. Alternatively, for years after 2012, we may require registries to submit all the individual data elements for CMS to calculate an eligible professional's reporting and performance rates as well as require registries to submit patient-level data on Medicare beneficiaries rather than aggregate data. We seek public comment on disallowing previously-qualified registries to submit data on Physician Quality Reporting System quality measures in future program years if it is found that the data the registries provide are significantly inaccurate.

(3) EHR-Based Reporting

For 2012 and beyond, we propose that eligible professionals who choose to participate in the Physician Quality Reporting System via the EHR-Based reporting mechanism have the option of submitting quality measure data obtained from their Physician Quality Reporting System qualified EHR to CMS either:
(1) Directly from his or her qualified EHR, in the CMS-specified manner, or
(2) indirectly from a qualified EHR data submission vendor (on the eligible professional's behalf), in the CMS-specified manner.

(A) Direct EHRs

(i) Proposed Requirements for the Direct EHR-Based Reporting Mechanism—Individual Eligible Professionals

For 2012 and beyond, we propose to retain the EHR-Based reporting mechanism via a qualified EHR (as defined in section (3)(b) of this section) for the purpose of satisfactorily reporting Physician Quality Reporting System quality measures. We propose the following requirements for individual eligible professionals associated with EHR-Based reporting: (1) Selection of a Physician Quality Reporting System qualified EHR product and (2) submission of Medicare clinical quality data extracted from the EHR directly to CMS, in the CMS-specified manner.

We propose that, in addition to meeting the appropriate criteria for satisfactory reporting of individual measures for the 2012 Physician Quality Reporting System EHR reporting option, eligible professionals who choose the EHR-Based reporting mechanism for the 2012 Physician Quality Reporting System would be required to have a Physician Quality Reporting System qualified EHR product. We understand that eligible professionals may have purchased Certified EHR Technology for purposes of reporting under the Medicare and Medicaid EHR Incentive Programs. Such Certified EHR Technology may or may not be qualified for purposes of the 2012 Physician Quality Reporting System. Eligible professionals would need to ensure that their Certified EHR Technology is also qualified for purposes of the 2012 Physician Quality Reporting System to participate in the Physician Quality Reporting System via the EHR-Based reporting mechanism for 2012. The certification process for EHR technology does not test the EHR product's ability to output a file that meets the Physician Quality Reporting System measures file specifications. We are currently exploring ways to further align these two programs' reporting requirements for future years so that Certified EHR Technology may be used to satisfy both the Medicare EHR Incentive Program and the Physician Quality Reporting System without any additional testing. For 2012, we propose to modify the current list of EHR vendors qualified under the Physician Quality Reporting System to indicate which of the qualified vendors' products have also received a certification for the purposes of the EHR Incentive Programs. We invite public comment on the 2012 proposed qualifications for direct EHRs.

(ii) 2012 Proposed Qualification Requirements for Direct EHR Products

For direct EHR products who wish to report 2012 Physician Quality Reporting System quality measures data on behalf of eligible professionals, we propose that a test of quality data submission from eligible professionals who wish to report 2012 quality measure data directly from their qualified EHR product would be required and we anticipate that this testing would occur in late 2012, immediately followed by the submission of the eligible professional's actual 2012 Physician Quality Reporting System data in early 2013. This entire final test/production data submission timeframe for 2012 is expected to be December 2012 through February 2013. We are currently vetting newly self-nominated EHR vendor products for possible qualification for the 2012 Physician Quality Reporting System program year. Similar to prior years, we expect to list the 2012 Physician Quality Reporting System qualified EHR products by January 2012. We will also be vetting those self-nominated EHR data submission vendors for possible qualification to submit 2012 Physician Quality Reporting System measures on eligible professionals' behalf under the EHR-Based reporting mechanism. We expect to list the entities that are EHR data submission vendors qualified to submit 2012 Physician Quality Reporting System EHR measures on eligible professionals' behalf by mid-2012.

For direct EHR vendors wishing to qualify for participation in the 2012 Physician Quality Reporting System-Medicare Incentive Pilot for the Medicare EHR Incentive Program (discussed in section IV.H. of this proposed rule), we propose a separate, accelerated vetting process for EHR vendors and their products. This vetting process will be the same process as the vetting process for EHR vendor products for the 2012 Physician Quality Reporting System that is currently underway. We will begin the vetting process for these additional EHR data submission vendors in the beginning of 2012 and anticipate that the vetting process be completed by Summer/Fall 2012.

We further propose that any EHR direct vendor interested in being ''qualified'' to submit quality data extracted from an EHR to CMS on eligible professionals' behalf for the 2012 Physician Quality Reporting System would be required to self-nominate. We anticipate that the self-nomination deadline will occur no later than December 31, 2011. We expect to post instructions for self-nomination by the 4th quarter of CY 2011 on the Physician Quality Reporting System section of CMS Web site.

(B) EHR Data Submission Vendors

(i) Proposed Requirements for the EHR Data Submission Vendor-based Reporting Mechanism—Individual Eligible Professionals

For 2012 and beyond, we propose to retain the EHR-Based reporting mechanism via a qualified EHR (as defined in 42 CFR 414.90(b)) for the purpose of satisfactorily reporting Physician Quality Reporting System quality measures. We propose the following requirements for individual eligible professionals associated with indirect EHR-Based reporting: (1) Selection of a Physician Quality Reporting System qualified EHR product and (2) submission of Medicare clinical quality data extracted from the EHR to a qualified ''EHR data submission vendor'' (which may include some current registries, EHR vendors, and other entities that are able to receive and transmit clinical quality data extracted from an EHR) to CMS, in the CMS-specified manner. For eligible professionals who choose to electronically submit Medicare clinical quality data extracted from their EHR to a qualified EHR data submission vendor, the EHR data submission vendor would then submit the Physician Quality Reporting System measures data to CMS in a CMS-specified manner on the eligible professional's behalf for the respective program year.

For 2012, we propose that in order for an eligible professional to submit Medicare clinical quality data extracted from his or her EHR to CMS via an EHR data submission vender, the eligible professional must enter into and maintain an appropriate legal arrangement with a qualified 2012 EHR data submission vendor that is capable of receiving and transmitting Medicare

clinical quality data extracted from an EHR. Such arrangements would provide for the EHR data submission vendor's receipt of beneficiary-specific data from the eligible professional and the EHR data submission vendor's disclosure of the beneficiary-specific data on behalf of the eligible professional to CMS. Thus, the EHR data submission vendor would act as a Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) Business Associate and agent of the eligible professional. Such agents are referred to as ''EHR data submission vendors.'' The ''EHR data submission vendors'' would have the requisite legal authority to provide beneficiary-specific data on the 2012 Physician Quality Reporting System EHR measures on behalf of the eligible professional to CMS for the Physician Quality Reporting System.

We also propose that eligible professionals choosing to participate in the 2012 Physician Quality Reporting System through the EHR-Based reporting mechanism via an EHR data submission vendor for 2012 must select a qualified Physician Quality Reporting System EHR data submission vendor and submit information on Physician Quality Reporting System EHR measures to the selected EHR data submission vendor in the form and manner, and by the deadline specified by the EHR data submission vendor. We invite public comment on the proposed qualification requirements on the 2012 proposed qualification requirements for individual eligible professionals using EHR data submission vendors to submit Physician Quality Reporting System quality measures data.

(i) 2012 Proposed Qualification Requirements for EHR Data Submission Vendors

Similar to our 2012 qualification requirements for direct EHR vendors, we propose that qualified EHR data submission vendors that wish to submit 2012 quality measures data obtained from an eligible professional's qualified EHR product to CMS on the eligible professional's behalf would be required to submit test data in late 2012 followed by the submission of the eligible professional's actual 2012 Physician Quality Reporting System data in early 2013. For data submission vendors wishing to qualify for participation in the 2012 Physician Quality Reporting System-Medicare Incentive Pilot for the Medicare EHR Incentive Program (discussed in section IV.H. of this proposed rule), we propose a separate, accelerated vetting process for EHR vendors and their products. This vetting process will be the same process as the vetting process for EHR vendor products for the 2012 Physician Quality Reporting System that is currently underway. We will begin the vetting process for these additional EHR data submission vendors in the beginning of 2012 and anticipate that the vetting process be completed by Summer/Fall 2012.

We further propose that any EHR data submission vendor interested in being ''qualified'' to submit quality data extracted from an EHR to CMS on eligible professionals' behalf for the 2012 Physician Quality Reporting System would be required to self-nominate. We anticipate that the self-nomination deadline will occur no later than December 31, 2011. We expect to post instructions for self-nomination by the 4th quarter of CY 2011 on the Physician Quality Reporting System section of CMS Web site.

We propose the following qualification requirements for EHR data submission vendors who wish to submit 2012 Physician Quality Reporting System quality measure data:

- Not be in a beta test form.
- Be in existence as of January 1, 2012.
- Have at least 25 active users.
- Participate in ongoing Physician Quality Reporting mandatory support conference calls hosted by CMS (approximately one call per month). Failure to attend more than one call per year would result in the removal of the EHR data submission vendor from the 2012 EHR qualification process.
- Have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit clinical quality data extracted to a CMS clinical data warehouse.
- Submit a test file containing dummy Medicare clinical quality data to a CMS clinical data warehouse via an identity management system specified by CMS during a timeframe specified by CMS. In 2011, the requirement to submit a test file could have contained real or dummy data. However, for privacy reasons, we have decided to only provide for the submission of test files containing dummy data. We have proposed revisions to 42 CFR 414.90 to reflect this change.
- Submit a file containing the eligible professional's 2012 Physician Quality Reporting System Medicare clinical quality data extracted from the EHR for the entire 12-month reporting period via the CMS-specified identify management system during the timeframe specified by us in early 2013.
- Provide at least 1 feedback report, based on the data submitted to them for the 2012 Physician Quality Reporting System incentive reporting period, and if technically feasible, provide at least 2 feedback reports throughout the year to participating eligible professionals.
- Be able to collect all needed data elements and transmit to CMS the data at the beneficiary level.
- Be able to separate out and report on Medicare Part B FFS patients.
- Provide the measure numbers for the quality measures on which the data submission vendor is reporting.
- Be able to transmit this data in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA).
- Comply with a CMS-specified secure method for data submission, such as submitting the EHR data submission vendor's data in an XML file through an identity management system specified by CMS or another approved method, such as use of appropriate NwHIN (Nationwide Health Information Network) specifications, if technically feasible.
- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the data submission vendor's receipt of patient-specific data from the eligible professionals, as well as the data submission vendor's disclosure of patient-specific data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the data submission vendor has authorized the data submission vendor to submit patient-specific data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the data submission vendor to submit Physician Quality Reporting System quality measures data to the data submission vendor and must meet any applicable laws, regulations, and contractual business associate agreements.
- Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which 2012 Physician Quality Reporting System EHR-Based submissions are founded or provide to CMS a copy of the actual data (upon request).
- 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 Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS would provide EHR data submission vendors a standard set of logic to calculate each measure and/or measures group they intend to report in 2012.

• Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the EHR data submission vendor intends to calculate. The data submission vendors would 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.

For EHR data submission vendors participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot for 2012 (discussed in section IV.H. of this proposed rule) and wish to also submit Medicare clinical quality data extracted from an EHR for the purposes of the 2012 Physician Quality Reporting System incentive, we propose that these EHR data submission vendors meet the following below requirements in addition to the requirements stated above:

• Be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level.

• Be able to calculate and submit measure-level reporting rates 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 TIN/NPI reports or, upon request the Medicare beneficiary data elements needed to calculate the reporting rates.

• Report the number of eligible instances (reporting denominator).

• Report the number of instances a quality service is performed (reporting 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 (eligible professional receives credit for reporting, not for performance), meaning the quality action was not performed for no valid reason as defined by the measure specification.

• Be able to transmit this data in a CMS-approved XML format.

• Submit an acceptable ''validation strategy'' to CMS by March 31, 2012. A validation strategy ascertains whether eligible professionals have submitted accurately and on at least the minimum number (80 percent) of their eligible patients, visits, procedures, or episodes for a given measure, which, as described in section (e)(2) of this section, is the minimum percentage of patients on which an eligible professional must report on any given measure. Acceptable validation strategies often include such provisions as the EHR data submission vendor 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, 2013 for the 2012 reporting year's data.

• Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the data submission vendor's receipt of patient-specific data from the eligible professionals, as well as the data submission vendor's disclosure of quality measure results and numerator and denominator data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.

• Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the data submission vendor has authorized the data submission vendor to submit quality measure results and numerator and denominator data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the data submission vendor to submit Physician Quality Reporting System quality measures data to the data submission vendor and must meet any applicable laws, regulations, and contractual business associate agreements.

• Use Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated.

• Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the EHR data submission vendor intends to calculate. The data submission vendors would 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.

We cannot, however, assume responsibility for the successful submission of data from eligible professionals' EHRs. In addition, eligible professionals who decide to submit the Physician Quality Reporting System measures directly from his or her EHR should begin attempting submission soon after the opening of the clinical data warehouse in order to assure the eligible professional has a reasonable period of time to work with his or her EHR and/or its vendors to correct any problems that may complicate or preclude successful quality measures data submission through that EHR.

We propose that for 2012, the EHR data submission vendor would submit clinical quality data on Medicare beneficiaries extracted from eligible professionals' EHRs to our designated database for the Physician Quality Reporting System using a CMS-specified record layout, which would be provided to the EHR data submission vendor by CMS. In addition, for purposes of also reporting 2012 Physician Quality Reporting System quality measures, the EHR data submission vendor would be required to submit patient level Medicare clinical quality data extracted from the eligible professional's EHR using the same CMS-specified record layout that qualified EHR products must be able to produce for purposes of an eligible professional directly submitting the 2012 Physician Quality Reporting System EHR measures to CMS.

We invite public comment on the proposed qualification requirements for EHR data submission vendors.

(C) Proposed Qualification Requirements for EHR Direct and Data Submission Vendors and Their Products for the 2013 Physician Quality Reporting System

As in prior years, unlike the qualification process for registries, EHR vendors, which include direct EHR vendors and EHR data submission vendors, are tested for qualification a year ahead of the program year in which the EHR vendor intends to submit Physician Quality Reporting System quality measures on behalf of individual

eligible professionals or where its product(s) are available for use by eligible professionals to submit Physician Quality Reporting System measures directly to CMS.

We propose EHR vendor testing for the 2013 Physician Quality Reporting System program year to qualify new EHR vendors and EHR data submission vendors and their EHR products for submission of Medicare beneficiary quality data extracted from EHR products to the CMS Medicare clinical quality data warehouse for the 2013 Physician Quality Reporting System. Specifically, we propose that in order for EHR vendors to be qualified to report 2013 Physician Quality Reporting System data to CMS, EHR vendors must meet the following requirements:

- Not be in a beta test form.
- Be in existence as of January 1, 2012.
- Have at least 25 active users.
- Participate in ongoing Physician Quality Reporting mandatory support conference calls hosted by CMS (approximately one call per month). Failure to attend more than one call per year would result in the removal of the EHR data submission vendor from the 2012 EHR qualification process.
- Indicate the reporting option the vendor seeks to qualify for its users to submit in addition to individual measures.
- Have access to the identity management system specified by CMS (such as, but not limited to, the Individuals Authorized Access to CMS Computer Systems, or IACS) to submit Medicare clinical quality data extracted to a CMS clinical data warehouse.
- Submit a test file containing dummy Medicare clinical quality data to a CMS clinical data warehouse via an identity management system specified by CMS during a timeframe specified by CMS. In 2011, the requirement to submit a test file could have contained real or dummy data. However, for privacy reasons, we have decided to only provide for the submission of test files containing dummy data. We have proposed revisions to 42 CFR 414.90 to reflect this change.
- Submit a file containing the eligible professional's 2012 Physician Quality Reporting System Medicare clinical quality data extracted from the EHR for the entire 12-month reporting period via the CMS-specified identify management system during the timeframe specified by us in early 2013.
- Provide at least 1 feedback report, based on the data submitted to them for the 2012 Physician Quality Reporting System incentive reporting period, and if technically feasible, provide at least two feedback reports throughout the year to participating eligible professionals.
- Be able to collect all needed data elements and transmit to CMS the data at the beneficiary level.
- Be able to separate out and report on Medicare Part B FFS patients.
- Provide the measure numbers for the quality measures on which the data submission vendor is reporting.
- Be able to transmit this data in a CMS-approved XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA).
- Comply with a CMS-specified secure method for data submission, such as submitting the EHR vendor's data in an XML file through an identity management system specified by CMS or another approved method, such as use of appropriate NwHIN (Nationwide Health Information Network) specifications, if technically feasible.
- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the data submission vendor's receipt of patient-specific data from the eligible professionals, as well as the data submission vendor's disclosure of patient-specific data on Medicare beneficiaries on behalf of eligible professionals who wish to participate in the Physician Quality Reporting System.
- Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the data submission vendor has authorized the data submission vendor to submit patient-specific data on Medicare beneficiaries to CMS for the purpose of Physician Quality Reporting System participation. This documentation must be obtained at the time the eligible professional signs up with the data submission vendor to submit Physician Quality Reporting System quality measures data to the data submission vendor and must meet any applicable laws, regulations, and contractual business associate agreements.
- Provide CMS access (upon request for health oversight purposes like validation) to review the Medicare beneficiary data on which 2012 Physician Quality Reporting System EHR-Based submissions are founded or provide to CMS a copy of the actual data (upon request).
- 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 Physician Quality Reporting System measure specifications and the CMS provided measure calculation algorithm, or logic, to calculate reporting rates or performance rates unless otherwise stated. CMS would provide EHR vendors a standard set of logic to calculate each measure and/or measures group they intend to report in 2012.
- Provide a calculated result using the CMS supplied measure calculation logic and XML file for each measure that the EHR vendor intends to calculate. The data submission vendors would 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.

This is the same self-nomination process described in the ''Requirements for Electronic Health Record (EHR) Vendors to Participate in the 2012 Physician Quality Reporting System EHR Program,'' posted on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/PQRS/20_AlternativeReporting Mechanisms.asp#TopOfPage.* For 2013, we propose that these requirements would apply not only for the purpose of a vendor's EHR product being qualified so that the product's users may submit 2013 Medicare beneficiary data extracted from the EHR for the 2013 Physician Quality Reporting System in 2014, but also for the purpose of a vendor's EHR product being qualified to electronically submit Medicare beneficiary data extracted from the EHR for reporting the electronic prescribing measure for the eRx Incentive Program 2013 incentive and 2014 payment adjustment. Similarly, we propose that requirements would apply not only for the purposes of an EHR data submission vendor being qualified to submit 2013 Medicare beneficiary data from eligible professionals' EHRs for the 2013 Physician Quality Reporting System in 2014 but also for the purpose of an EHR data submission vendor being qualified to electronically submit Medicare beneficiary data extracted from the EHR for reporting the electronic prescribing measure for the eRx Incentive Program 2013 incentive and 2014 payment adjustment.

We propose that if an EHR vendor misses more than one mandatory support call or meeting, the vendor and their product and/or EHR data submission vendor would be disqualified for the Physician Quality Reporting System reporting year, which is covered by the call.

For the 2013 Physician Quality Reporting System, we propose that previously qualified and new vendors and/or EHR data submission vendors would need to incorporate any new EHR measures (that is, electronically-specified measures), as well as update their electronic measure specifications and data transmission schema should either or both change, finalized for to the Physician Quality Reporting System for 2013 if they wish to maintain their Physician Quality Reporting System qualification.

We further propose that any EHR vendor interested in having one or more of their EHR products ''qualified'' to submit quality data extracted from their EHR products to the CMS Medicare clinical quality data warehouse for the 2013 Physician Quality Reporting System would be required to submit their self-nomination statement by January 31, 2012. Whereas, in prior program years, EHR vendors have submitted self-nomination statements via mail, we propose to have EHR vendors submit self-nomination statements via a Web-based tool, if technically feasible for us to develop such a tool. We believe use of a Web-based tool to self-nominate is a more efficient method of collecting self-nomination statements. However, if use of a Web-based tool is not technically feasible, as in prior years, EHR vendors will submit self-nomination statements via e-mail. We expect to post instructions for submitting the self-nomination statement and the 2013 EHR vendor requirements in the 4th quarter of CY 2011. Specifically, for the 2013 Physician Quality Reporting System, in order to ensure EHR vendors' interest in participating in the 2013 Physician Quality Reporting System, we propose that only EHR vendors that self-nominate to participate in the EHR Program testing during calendar year 2012 would be considered qualified EHR vendors for the 2013 Physician Quality Reporting System.

We invite public comment on the proposed qualification requirements for EHR vendors and their products for the 2013 Physician Quality Reporting System.

e. Incentive Payments for the 2012 Physician Quality Reporting System

In accordance with 42 CFR 414.90(c)(3), eligible professionals that satisfactorily report 2012 Physician Quality Reporting System measures can qualify for an incentive equal to 0.5 percent of the total estimated part B allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice participating in the GPRO, the group practice) during the applicable reporting period. We are proposing to modify the incentive payment language in 42 CFR 414.90 to provide language more consistent with section 1848(k) of the Act.

(1) Proposed Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals via Claims

Section 1848(m)(3)(A) of the Act established the criteria for satisfactorily submitting data on individual quality measures as at least three measures in at least 80 percent of the cases in which the measure is applicable. For claims-based reporting, if fewer than three measures are applicable to the services of the professional, the professional may meet the criteria by submitting data on one or two measures for at least 80 percent of applicable cases where the measures are reportable. For years after 2009, section 1848(m)(3)(D) of the Act authorizes the Secretary, in consultation with stakeholders and experts, to revise the criteria for satisfactorily reporting data on quality measures. Accordingly, we propose the following criteria for satisfactory reporting via the claims-based reporting mechanism for individual eligible professionals specializing in internal medicine, family practice, general practice, or cardiology:

- Report on at least one Physician Quality Reporting System core measure as identified in Table 29.
- Report on at least two additional measures that apply to the services furnished by the professional.
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

For all other eligible professionals, we propose the following criteria for satisfactory reporting via the claims-based reporting mechanism:

- Report on at least three measures that apply to the services furnished by the professional.
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We believe it would be easier for eligible professionals to find applicable measures on which to report if measures were grouped according its applicability to medical specialties. We then seek to move towards having specialties report on certain measures that are relevant to the respective specialty. We have recognized the promotion of the prevention of cardiovascular conditions as a top priority and therefore propose to start to group individual measures with measures that promote cardiovascular care. As such, the Physician Quality Reporting System core measures that we propose in Table 29 are aimed at promoting the prevention of cardiovascular conditions. In an effort to promote the prevention of cardiovascular conditions, we are proposing that eligible professionals specializing in internal medicine, family practice, general practice, or cardiology be required to report on at least one proposed Physician Quality Reporting System core measure. We chose the aforementioned specialties because we believe the Physician Quality Reporting System core measures are most relevant to those specialties. Since we believe that eligible professionals in those specialties would likely report on the proposed Physician Quality Reporting System core measures regardless of the proposed requirement to report on at least one Physician Quality Reporting System core measure, we believe that the this requirement would not result in an increased burden to these specialties. In future years, we hope to develop a similar reporting requirement and core set of measures for other specialties.

We also considered including geriatricians in the proposed Physician Quality Reporting System core measure reporting requirement for 2012. However, we would like to ensure that the proposed 2012 Physician Quality Reporting System core measures would be sufficiently applicable to geriatric physicians before making such a proposal. We seek public comment as to whether geriatricians should be included as a specialty required to report at least one proposed 2012 Physician Quality Reporting System core measure. In addition, we invite public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System proposed core measure reporting requirement.

As stated previously, we have proposed the requirement of the reporting of Physician Quality Reporting System core measures for certain specialties to introduce measures reporting according to specialty for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology. However, we are not proposing this core measure requirement for all other specialties. Therefore, for all other specialties, we are proposing to retain similar reporting criteria as finalized for the in the 2011 MPFS final rule.

Specifically, under our authority under section 1848(m)(3)(D) of the Act to revise the reporting criteria for satisfactory reporting, for all other eligible professionals, we propose the following criteria for satisfactory reporting via the claims-based reporting mechanism:

- Report on at least three measures that apply to the services furnished by the professional. Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

To the extent that an eligible professional has fewer than three Physician Quality Reporting System measures that apply to the eligible professional's services and the eligible professional is reporting via the claims-based reporting mechanism, we propose that the eligible professional would be able to meet the criteria for satisfactorily reporting data on individual quality measures by meeting the following two criteria—

- Report on all measures that apply to the services furnished by the professional (that is one to two measures); and
- Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

As in prior years, we also propose that, for 2012, an eligible professional may also report on fewer than three measures, if less than three apply. However, an eligible professional who reports on fewer than three measures through the claims-based reporting mechanism may be subject to the Measure Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. This process was applied in prior years, including the 2011 Physician Quality Reporting System. Under the proposed MAV process, when an eligible professional reports on fewer than 3 measures, we propose 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). We further propose that if an eligible professional who reports on fewer than 3 measures in 2012 reports on a measure that is part of an identified cluster of closely related measures and did not report on any other measure that is part of that identified cluster of closely related measures, then the eligible professional would not qualify as a satisfactory reporter in the 2012 Physician Quality Reporting System or earn an incentive payment. We propose that these criteria for satisfactorily reporting data on fewer than three individual quality measures would apply for the claims-based reporting mechanism only because, unlike registry and EHR-Based reporting, the reporting of Physician Quality Reporting System quality measures via claims is not handled by an intermediary but rather directly by the eligible professional.

For 2012, in order to encourage reporting on measures that are applicable to the eligible professional's practice as well as encourage eligible professionals to perform the clinical quality actions specified in the measures, we propose not to count measures that are reported through claims that have a 0 percent performance rate. That is, if the recommended clinical quality action, as indicated in the numerator of the quality measure, is not performed on at least one patient for a particular measure or measures group reported by the eligible professional via claims, we will not count the measure (or measures group) as a measure (or measures group) reported by an eligible professional. This requirement is also consistent with the proposed registry and EHR-Based reporting (see the following section (e)(3)) criteria for satisfactory reporting that are proposed in this section.

The proposed 2012 criteria for satisfactory reporting of data on individual Physician Quality Reporting System quality measures for individual eligible professionals are summarized in the following Tables 18 and 2, and are arranged by reporting mechanism and reporting period.

TABLE 18—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA CLAIMS FOR THE FOLLOWING SPECIALTIES: INTERNAL MEDICINE FAMILY PRACTICE, GENERAL PRACTICE, AND CARDIOLOGY

Reporting mechanism	Reporting criteria	Reporting period
Claims-based reporting.	• Report at least three Physician Quality Reporting System measures, which consist of one Physician Quality Reporting System core measure + 2 additional measures of the eligible professional's choosing; OR. • If less than three measures apply to the eligible professional, 1–2 measures, of which at least 1 measure must consist of a Physician Quality Reporting System core measure; AND • Report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. • Measures with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.

TABLE 19—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA CLAIMS FOR ALL OTHER ELIGIBLE PROFESSIONALS NOT IDENTIFIED IN TABLE 18

Reporting mechanism	Reporting criteria	Reporting period
Claims-based reporting.	• Report at least three Physician Quality Reporting System measures; OR • If less than three measures apply to the eligible professional, 1–2 measures; AND • Report each measure for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.. • Measures with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.

We invite public comment on the proposed criteria for satisfactory reporting of individual measures by individual eligible professionals via claims for the 2012 Physician Quality Reporting System.

(2) Proposed 2012 Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals via Registry

Under our authority of section 1848(m)(3)(D) of the Act to revise the reporting criteria for the satisfactory reporting of measures, we propose the following criteria for satisfactory reporting via the registry-based reporting mechanism: (1) Criteria for individual eligible professionals practicing in internal medicine, family practice, general practice, or cardiology and (2) criteria for all other eligible professionals. For the reasons stated previously, we are distinguishing eligible professionals in internal medicine, family practice, general practice, or cardiology from all other eligible professionals for the purposes of establishing criteria for satisfactory reporting. Therefore, for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, we propose the following criteria for satisfactory reporting:

• Report on at least one Physician Quality Reporting System core measure as identified in Table 29.

• Report on at least two additional measures that apply to the services furnished by the professional.

• Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

For the same reasons stated for establishing different reporting criteria for all other eligible professionals under the claims-based reporting mechanism, we propose the following criteria for satisfactory reporting via the registry-based reporting mechanism:

• Report on at least three measures that apply to the services furnished by the professional.

• Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We also considered including geriatricians in the proposed Physician Quality Reporting System core measure reporting requirement via the registry-based reporting mechanism for 2012. However, as stated previously, we would like to ensure that the proposed 2012 Physician Quality Reporting System core measures would be sufficiently applicable to geriatric physicians before making such a proposal. We seek public comment as to whether geriatricians should be included as a specialty required to report at least one proposed 2012 Physician Quality Reporting System core measure. In addition, we seek public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System proposed core measure reporting requirement.

In addition, as in prior years, for 2012, we propose not to count measures that are reported through registries that have a 0 percent performance rate, calculated by dividing the measure's numerator by the measure's denominator. That is, if the recommended clinical quality action, that is the action denoted in the quality measure's numerator, is not performed on at least one patient for a particular measure or measures group reported by the eligible professional via registry, we will not count the measure (or measures group) as a measure (or measures group) reported by an eligible professional. We propose to disregard measures (or measures groups) that are reported through a registry that have a 0 percent performance rate in the 2012 Physician Quality Reporting System, because we are assuming that the measure was not applicable to the eligible professional and was likely reported from EHR-derived data (or from data mining) and was unintentionally submitted from the registry to us. We also seek to avoid the possibility of intentional submission of spurious data solely for the purpose of receiving an incentive payment for reporting.

The proposed 2012 criteria for satisfactory reporting of data on individual Physician Quality Reporting System quality measures for individual eligible professionals are summarized in the following Tables 20 and 21, and are arranged by reporting mechanism and reporting period.

TABLE 20—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA REGISTRY FOR THE FOLLOWING SPECIALTIES: INTERNAL MEDICINE FAMILY PRACTICE, GENERAL PRACTICE, AND CARDIOLOGY

Reporting mechanism	Reporting criteria	Reporting period
Registry-based reporting.	• Report at least three Physician Quality Reporting System measures, which consist of 1 Physician Quality Reporting System core measure + 2 additional measures of the eligible professional's choosing AND • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. • Measures with a 0% performance rate will not be counted.	January 1, 2012—December 31, 2012.

TABLE 21—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA REGISTRY FOR ALL OTHER ELIGIBLE PROFESSIONALS NOT IDENTIFIED IN TABLE 20

Reporting mechanism	Reporting criteria	Reporting period
Registry-based reporting.	• Report at least three Physician Quality Reporting System measures AND • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. • Measures with a 0% performance rate will not be counted	January 1, 2012—December 31, 2012.

We invite public comment on the proposed criteria for satisfactory reporting of individual quality measures for individual eligible professionals via registry.(3) Proposed Criteria for Satisfactory Reporting of Individual Quality Measures for Individual Eligible Professionals via EHR

Section 1848(m)(3)(A) of the Act established the criteria for satisfactorily submitting data on individual quality measures as at least three measures in at least 80 percent of the cases in which the measure is applicable. For years after 2009, section 1848(m)(3)(D) of the Act authorizes the Secretary, in consultation with stakeholders and experts, to revise the criteria for satisfactorily reporting data on quality measures. Accordingly, we propose the following options for satisfactory reporting of individual quality measures by individual eligible professionals participating in the 2012 Physician Quality Reporting System via the EHR-Based reporting mechanism:

First, we propose that an eligible professional would meet the criteria for satisfactory reporting under the Physician Quality Reporting System if the eligible professional, using a Physician Quality Reporting System ''qualified'' EHR product (if the eligible professional is also participating in the EHR Incentive Program via the proposed Physician Quality Reporting System-EHR Incentive Pilot discussed in section IV.H. of this proposed rule, the eligible professional's EHR product must also be Certified EHR Technology), reports on three proposed core measures for 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which each measure applies as identified in Table 31 in this section of this proposed rule, which are identical to the Medicare EHR Incentive Program core measures included in Table 7 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44410). Insofar as the denominator for one or more of the core measures is 0, implying that the eligible professional's patient population is not addressed by these measures, we propose that eligible professionals would be required to report up to three proposed alternate core measures as identified in Table 31 in this section of this proposed rule and which are identical to the Medicare EHR Incentive Program alternate core measures included in Table 7 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44410). In addition, we propose that the eligible professional would be required to report on three additional measures of their choosing that are available for the Medicare EHR Incentive Program in Table 6 of the Medicare and Medicaid EHR Incentive Program final rule (75 FR 44398 through 44408) (as identified in Table 31 in this section of this proposed rule).

With respect to reporting on the proposed measure titled ''Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up'', listed in Table 31 of this proposed rule, there are two parameters in the measure denominator description: Age 65 and older BMI and Age 18–64 BMI. For the purpose of reporting this measure under the Physician Quality Reporting System, we propose to count the reporting of this measure if at least one of the two parameters does not contain a 0 percent performance rate. In addition, with respect to reporting on the proposed measure titled ''Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention'', also listed in Table 31 of this proposed rule, the measure is divided into two pairs: a. Tobacco Use Assessment and b. Tobacco Cessation Intervention. For the purpose of reporting this measure under the Physician Quality Reporting System, we propose to count the reporting of this measure if at least one of the two pairs does not contain a 0 percent performance rate.

Section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting and EHR Reporting''), as added by section 3002(d) of the Affordable Care Act, requires us to move towards the integration of EHR measures with respect to the Physician Quality Reporting System. Section 1848(m)(7) of the Act specifies that by no later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under the Physician Quality Reporting System with reporting requirements under subsection (o) of section 1848 of the Act relating to the meaningful use of EHRs. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which would both demonstrate—

(i) Meaningful use of an EHR for purposes of the Medicare EHR Incentive Program; and

(ii) Quality of care furnished to an individual; and

(B) Such other activities as specified by the Secretary.

We propose the aforementioned criteria for satisfactory reporting via an EHR, which is identical to the criteria for achieving meaningful use for reporting clinical quality measures under the EHR Incentive Program as finalized in the Medicare and Medicaid Electronic Health Record Incentive Program final rule (75 FR 44409 through 44411), in an effort to align the Physician Quality Reporting System with the Medicare EHR Incentive Program.

In addition to the reporting criteria proposed previously, we propose alternative reporting criteria for satisfactory reporting using the EHR-Based reporting mechanism that is similar to the criteria finalized in the CY 2011 MPFS Final Rule with comment period (75 FR 73497 through 73500). For the reasons set forth for establishing different criteria for satisfactory reporting via claims and registry, we are adopting two different criteria for satisfactory reporting, depending on an eligible professional's specialty. For eligible professionals specializing in internal medicine, family practice, general practice, and cardiology, we propose the following criteria:

- Report on ALL proposed Physician Quality Reporting System core measure as identified in Table 29.
- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

We understand that by proposing to require eligible professionals specializing in internal medicine, family practice, general practice, and cardiology to report all Physician Quality Reporting System core measures, we would be requiring such professionals to report more measures than eligible professionals who do not practice within those specialties. We believe, however, that proposing to require these specialists to report of all Physician Quality Reporting System core measures would not add an additional burden to these eligible professionals because the reporting of measures is done entirely through the EHR. Furthermore, because we are proposing to require these specialties to report on all Physician Quality Reporting System core measures and recognize that some of the proposed Physician Quality Reporting System core measures may not be applicable to all of these eligible professionals' specialties, we propose to allow the reporting of these proposed Physician Quality Reporting System core measures with a 0 percent performance rate. That is, the reporting of a Physician Quality Reporting System core measure that is not applicable to the eligible professional's practice in this instance will not preclude an eligible professional from meeting the criteria for satisfactory reporting.

We also considered including geriatricians in the proposed Physician Quality Reporting System core measure reporting requirement for 2012. However, we would like to ensure that the proposed 2012 Physician Quality Reporting System core measures would be sufficiently applicable to geriatric physicians before making such a proposal. We seek public comment as to whether geriatricians should be included as a specialty required to report at least one proposed 2012 Physician Quality Reporting System core measure via EHR-Based reporting. In addition, we invite public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System proposed core measure reporting requirement.

For the reasons we stated previously for creating separate reporting criteria all other eligible professionals for claims and registry reporting, we propose the following criteria for satisfactory reporting using the EHR-Based reporting mechanism:

- Report on at least three Physician Quality Reporting System EHR measures of the eligible professional's choosing; and
- Report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients for whom services were furnished during the reporting period to which the measure applies.

The proposed methods for satisfactory reporting via EHR for the 2012 Physician Quality Reporting System are described in the following Tables 22 and 23.

TABLE 22—2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA EHR FOR THE FOLLOWING SPECIALTIES: INTERNAL MEDICINE, FAMILY PRACTICE, GENERAL PRACTICE, AND CARDIOLOGY

Reporting mechanism	Reporting criteria	Reporting period
EHR—Aligning with the Medicare EHR Incentive Program.	• Reports on ALL three Medicare EHR Incentive Program core measures (as identified in Table 31 of this proposed rule). • If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three Medicare EHR Incentive Program alternate core measures (as identified in Table 31 of this proposed rule); AND • Report on three (of the 38 additional measures available for the Medicare EHR Incentive Program.	January 1, 2012–December 31, 2012.
EHR	• Report on ALL Physician Quality Reporting System core measures AND • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. • Measures with a 0% performance rate will not be counted, unless the measure is a Physician Quality Reporting System core measure.	January 1, 2012–December 31, 2012.

TABLE 23—2012 CRITERIA FOR SATISFACTORY REPORTING OF DATA ON INDIVIDUAL PHYSICIAN QUALITY REPORTING SYSTEM QUALITY MEASURES VIA EHR FOR ALL OTHER ELIGIBLE PROFESSIONALS NOT IDENTIFIED IN TABLE 22

Reporting mechanism	Reporting criteria	Reporting period
EHR—Aligning with the Medicare EHR Incentive Program.	• Reports on ALL three Medicare EHR Incentive Program core measures (as identified in Table 31 of this proposed rule). • If the denominator for one or more of the Medicare EHR Incentive Program core measures is 0, report on up to three Medicare EHR Incentive Program alternate core measures (as identified in Table 31 of this proposed rule); AND • Report on three (of the 38) additional measures available for the Medicare EHR Incentive Program.	January 1, 2012–December 31, 2012.
EHR	• Report at least three Physician Quality Reporting System measures AND • Report each measure for at least 80% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. • Measures with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.

We invite public comment on the proposed criteria for satisfactory reporting of individual quality measures by individual eligible professionals via an EHR-Based reporting mechanism in the 2012 Physician Quality Reporting System. (4) Proposed Criteria for Satisfactory Reporting of Measures Groups via Claims—Individual Eligible Professionals

At § 414.90(b) ''measures group'' is defined as ''a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common.'' For 2012 and beyond, we propose that individual eligible professionals have the option to report measures groups in addition to individual quality measures to qualify for the Physician Quality Reporting System incentive, using claims or registries.

For the reasons we are proposing different criteria for satisfactorily reporting individual quality measures depending on specialty, specifically our desire to introduce core measures applicable to certain specialties and promote cardiovascular care, we are proposing two different criteria for satisfactorily reporting measures groups. We propose the following criteria for satisfactory reporting of 2012 Physician Quality Reporting System measures groups:

We propose that eligible professionals specializing in internal medicine, family practice, general practice, and cardiology may meet the criteria for satisfactory reporting of Physician Quality Reporting System measures groups via claims by reporting in the following manner:

• Report at least one Physician Quality Reporting System measures group; and

• If the measures group does not contain at least one Physician Quality core measure, then one Physician Quality core measure; and

• For each measures group and, if applicable, Physician Quality Reporting System core measure reported, report on at least 30 Medicare Part B FFS patients for each measures group that is reported.

• Measures groups containing a measure with a 0 percent performance rate will not be counted.

We also propose that eligible professionals specializing in internal medicine, family practice, general practice, and cardiology may meet the criteria for satisfactorily reporting Physician Quality Reporting System measures groups via claims by reporting in the following manner:

• Report at least one Physician Quality Reporting System measures group; but

• If the measures group does not contain at least one Physician Quality Reporting System core measure, then one Physician Quality core measure.

• For each measures group and, if applicable, Physician Quality Reporting System core measure reported, report on 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 no less than 15 Medicare Part B PFS patients for each measures group reported.

• Measures groups containing a measure with a 0 percent performance rate will not be counted.

For all other eligible professionals, in order to meet the criteria for satisfactory reporting of Physician Quality Reporting measures groups via claims, we propose that the eligible professional must:

• Report at least one Physician Quality Reporting System measures group.

• Report on at least 30 Medicare Part B FFS patients for each measures group that is reported.

• Measures groups containing a measure with a 0 percent performance rate will not be counted.

Alternatively, eligible professionals not specializing in internal medicine, family practice, general practice, and cardiology may meet the criteria for satisfactorily reporting Physician Quality Reporting System measures groups via claims by reporting in the following manner:

• Report at least one Physician Quality Reporting System measures group.

• For each measures group reported, report each on 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 no less than 15 Medicare Part B PFS patients for each measures group reported.

• Measures groups containing a measure with a 0 percent performance rate will not be counted.

Aside from the Physician Quality Reporting System core measure reporting requirement for eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, we are proposing to retain the same criteria for satisfactory reporting of measures groups via claims as the 2011 criteria for satisfactory reporting of measures groups via claims for the 12-month reporting period that was finalized in the 2011 MPFS Final Rule with comment period. Therefore, as in 2011, an eligible professional must satisfactorily report on all individual measures within the measures group in order to meet the criteria for satisfactory reporting via measures groups. We are retaining the same criteria because

eligible professionals are already familiar with these reporting criteria, which we believe will in turn lead to a greater chance that eligible professionals meet the criteria for satisfactory reporting.

As with the reporting of Physician Quality Reporting System individual measures, we also considered including geriatricians as one of specialties we proposed previously with regard to the proposed Physician Quality Reporting System core measure reporting requirement for measures groups. However, we would like to ensure that the proposed 2012 Physician Quality Reporting System core measures are sufficiently applicable to geriatric physicians before proposing to include them under the proposed requirement. We seek public comment as to whether geriatricians should be included as a specialty required to report at least 1 proposed 2012 Physician Quality Reporting System core measure for measures group reporting. In addition, we seek public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement for measures groups.

For 2012, in order to ensure that the Physician Quality Reporting System measures on which eligible professionals report are applicable to their respective practices, we propose not to count measures within measures groups that are reported through claims or registry that have a 0 percent performance rate. That is, if the recommended clinical quality action is not performed on at least one patient for a particular measure reported by the eligible professional via claims or registry, we will not count the measures groups as a measures group reported by an eligible professional. Furthermore, this proposed requirement is consistent with the proposed reporting options for individual quality measures, which are discussed previously. Since we are proposing to retain the requirement that an eligible professional must satisfactorily report on all individual measures contained within a measures group in order to meet the criteria for satisfactory reporting via measures groups, if an eligible professional reports a measure contained within a measures group with a 0 percent performance rate, the eligible professional will fail to meet the criteria for the satisfactory reporting of measures groups.

The 2012 proposed criteria for satisfactory reporting of measures groups via claims for individual eligible professionals are described in the following Tables 24 and 25.

TABLE 24—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA CLAIMS FOR THE FOLLOWING SPECIALTIES: INTERNAL MEDICINE, FAMILY PRACTICE, GENERAL PRACTICE, AND CARDIOLOGY

Reporting mechanism	Reporting criteria	Reporting period
Claims	• Report at least 1 Physician Quality Reporting System measures group; AND • If the measures group does not contain at least 1 Physician Quality core measure, then report 1 Physician Quality core measure; AND • Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 30 Medicare Part B FFS patients. • Measures groups containing a measure with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.
Claims	• Report at least 1 Physician Quality Reporting System measures group; AND • If the measures group does not contain at least 1 Physician Quality core measure, then report 1 Physician Quality core measure; AND • Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 50% 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% performance rate will not be counted.	January 1, 2012–December 31, 2012.

TABLE 25—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA CLAIMS FOR ALL OTHER ELIGIBLE PROFESSIONALS NOT IDENTIFIED IN TABLE 24

Reporting mechanism	Reporting criteria	Reporting period
Claims	• Report at least 1 Physician Quality Reporting System measures group; AND • Report each measures group for at least 30 Medicare Part B FFS patients. • Measures groups containing a measure with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.
Claims	• Report at least 1 Physician Quality Reporting System measures group; • Report each measures group for at least 50% of the eligible professional's Medicare Part B FFS patients seen during the reporting period to whom the measures group applies; BUT	January 1, 2012–December 31, 2012.

TABLE 25—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA CLAIMS FOR ALL OTHER ELIGIBLE PROFESSIONALS NOT IDENTIFIED IN TABLE 24—Continued

Reporting mechanism	Reporting criteria	Reporting period
	• 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% performance rate will not be counted.	

An eligible professional could also potentially qualify for the Physician Quality Reporting System incentive payment by satisfactorily reporting both individual measures and measures groups. However, only one incentive payment will be made to the eligible professional. We invite public comment on the proposed 2012 criteria for satisfactory reporting of measures groups via claims for individual eligible professionals.

(5) Proposed 2012 Criteria for Satisfactory Reporting of Measures Groups via Registry—Individual Eligible Professionals

As with the reporting of measures groups via claims, we are proposing different criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry depending on the eligible professional's specialty. For eligible professionals specializing in internal medicine, family practice, general practice, or cardiology, in order to meet the criteria for the satisfactory reporting of Physician Quality Reporting measures groups via registry, during the proposed 12-month reporting period, we propose that the eligible professional must—

• Report at least 1 Physician Quality Reporting System measures group; AND

• If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND

• Report on at least 30 Medicare Part B FFS patients for each measures group and, if applicable, Physician Quality Reporting System core measure reported.

• Measures groups containing a measure with a 0% performance rate will not be counted.

Alternatively, we propose that the eligible professional specializing in internal medicine, family practice, general practice, or cardiology may meet the criteria for the satisfactory reporting of Physician Quality measures groups via registry by doing the following during the proposed 12-month reporting period:

• Report at least one Physician Quality Reporting System measures group; AND

• If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND

• Report each measures group and, if applicable, Physician Quality Reporting System core measure 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% performance rate will not be counted.

In order to meet the criteria for the satisfactory reporting of Physician Quality Reporting measures groups via registry, during the proposed 6-month reporting period, we propose that theeligible professional must—

• Report at least one Physician Quality Reporting System measures group; AND

• If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND

• Report each measures group and, if applicable, Physician Quality Reporting System core measure 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% performance rate will not be counted.

For all other eligible professionals, in order to meet the criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry, we propose that, during the proposed 12-month reporting period, the eligible professional must—

• Report at least 1 Physician Quality Reporting System measures group; AND

• Report each measures group for at least 30 Medicare Part B FFS patients.

• Measures groups containing a measure with a 0% performance rate will not be counted.

Alternatively, we propose that an eligible professional not specializing in internal medicine, family practice, general practice, or cardiology may meet the criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry by doing the following during the proposed 12-month reporting period:

• Report at least one Physician Quality Reporting System measures group; AND

• For each measures group reported, report on 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 no less than 15 patients for each measures group reported.

For all other eligible professionals, in order to meet the criteria for the satisfactory reporting of Physician Quality Reporting System measures groups via registry during the proposed 6-month reporting period, we propose that, during the proposed 6-month reporting period, the eligible professional must—

• Report at least 1 Physician Quality Reporting System measures group; AND

• For each measures group reported, report on 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 least 8 Medicare Part B FFS patients for each measures group reported.

• Measures groups containing a measure with a 0% performance rate will not be counted.

Aside from the Physician Quality Reporting System core measure reporting requirement for eligible professionals specializing in internal medicine, family practice, general

practice, or cardiology, we are proposing to retain the same criteria for satisfactory reporting of measures groups via registry as the 2011 criteria for satisfactory reporting of measures groups via registry finalized in the 2011 MPFS Final Rule with comment period. Therefore, as in 2011, an eligible professional must satisfactorily report on all individual measures within the measures group in order to meet the criteria for satisfactory reporting via measures groups. We are retaining the same criteria because we eligible professionals are already familiar with this reporting criteria, which we believe will in turn lead to a greater chance that eligible professionals meet the criteria for satisfactory reporting.

As with the reporting of Physician Quality Reporting System individual measures, we also considered including geriatricians as one of specialties we proposed previously with regard to the proposed Physician Quality Reporting System core measure reporting requirement for measures groups. However, we would like to ensure that the proposed 2012 Physician Quality Reporting System core measures are sufficiently applicable to geriatric physicians before proposing to include them under the proposed requirement. We seek public comment as to whether geriatricians should be included as a specialty required to report at least 1 proposed 2012 Physician Quality Reporting System core measure for measures group reporting. In addition, we seek public comment on whether other specialties should be included in the 2012 Physician Quality Reporting System core measure reporting requirement for measures groups.

For 2012, in order to ensure that the Physician Quality Reporting System measures on which eligible professionals report are applicable to their respective practices, we propose not to count measures within measures groups that are reported through claims or registry that have a 0 percent performance rate. That is, if the recommended clinical quality action is not performed on at least one patient for a particular measure reported by the eligible professional via claims or registry, we will not count the measures groups as a measures group reported by an eligible professional. Furthermore, this proposed requirement is consistent with the proposed reporting options for individual quality measures, which are discussed previously. Since we are proposing to retain the requirement that an eligible professional must satisfactorily report on all individual measures contained within a measures group in order to meet the criteria for satisfactory reporting via measures groups, if an eligible professional reports a measure contained within a measures group with a 0 percent performance rate, the eligible professional will fail to meet the criteria for the satisfactory reporting of measures groups.

The proposed 2012 criteria for satisfactory reporting of data on measures groups are summarized in the following Tables 26 through 27 and are arranged by reporting mechanism and reporting period.

TABLE 26—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA REGISTRY FOR THE FOLLOWING SPECIALTIES: INTERNAL MEDICINE, FAMILY PRACTICE, GENERAL PRACTICE AND CARDIOLOGY

Reporting mechanism	Reporting criteria	Reporting period
Registry	• Report at least 1 Physician Quality Reporting System measures group; AND • If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND • Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 30 Medicare Part B FFS patients. • Measures groups containing a measure with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.
Registry	• Report at least 1 Physician Quality Reporting System measures group; • If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND • Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 80% 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% performance rate will not be counted.	January 1, 2012–December 31, 2012.
Registry	• Report at least 1 Physician Quality Reporting System measures group; • If the measures group does not contain at least 1 Physician Quality core measure, then 1 Physician Quality core measure; AND • Report each measures group and, if applicable, Physician Quality Reporting System core measure for at least 80% 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 at least 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% performance rate will not be counted.	July 1, 2012–December 31, 2012.

TABLE 27—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING ON MEASURES GROUPS VIA REGISTRY FOR ALL OTHER ELIGIBLE PROFESSIONALS NOT IDENTIFIED IN TABLE 26

Reporting mechanism	Reporting criteria	Reporting period
Registry	• Report at least 1 Physician Quality Reporting System measures group; AND • Report each measures group for at least 30 Medicare Part B FFS patients. • Measures groups containing a measure with a 0% performance rate will not be counted.	January 1, 2012–December 31, 2012.
Registry	• Report at least 1 Physician Quality Reporting System measures group; AND • Report each measures group for at least 80% 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 at least 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% performance rate will not be counted.	January 1, 2012–December 31, 2012.
Registry	• Report at least 1 Physician Quality Reporting System measures group; AND • Report each measures group for at least 80% 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% performance rate will not be counted.	July 1, 2012–December 31, 2012.

An eligible professional could also potentially qualify for the Physician Quality Reporting System incentive payment by satisfactorily reporting both individual measures and measures groups. However, only one incentive payment will be made to the eligible professional. We invite public comment on the proposed criteria for satisfactory reporting of measures groups for individual eligible professionals.

(6) Proposed 2012 Criteria for Satisfactory Reporting on Physician Quality Reporting System Measures by Group Practices Under the GPRO

As stated previously, instead of participating as an individual eligible professional, an eligible professional in a group practice may participate in the Physician Quality Reporting System under the Physician Quality Reporting System GPRO. However, an individual eligible professional who is affiliated with a group practice participating in the Physician Quality Reporting System GPRO that satisfactorily submits Physician Quality Reporting System quality measures will only be able to earn an incentive as part of the group practice and not as an individual eligible professional.

As stated previously, we propose that group practices interested in participating in GPRO must self-nominate. As stated in the ''Proposed Reporting Period'' in section IV.F.2.c. of this proposed rule, for group practices selected to participate in the Physician Quality Reporting System GPRO for 2012, we propose a 12-month reporting period beginning January 1, 2012. For 2012, we propose to use the same GPRO reporting methods that we have used in prior years. Specifically, we propose that group practices participating in GPRO submit information on measures within a proposed common set of 40 NQF-endorsed quality measures using a web interface based on the GPRO Tool used in the 2011 Physician Quality Reporting System GPRO. As part of the data submission process for 2012 GPRO, we propose that during 2012, each group practice would be required to report quality measures with respect to services furnished during the 2012 reporting period (that is, January 1, 2012, through December 31, 2012) on an assigned sample of Medicare beneficiaries. Once the beneficiary assignment has been made for each group practice, which we anticipate will be done during the fourth quarter of 2012, we propose to provide each group practice selected to participate in the Physician Quality Reporting System GPRO with access to a web interface that would include the group's assigned beneficiary samples and the final GPRO quality measures. We propose to pre-populate the web interface with the assigned beneficiaries' demographic and utilization information based on all of their Medicare claims data. The group practice would be required to populate the remaining data fields necessary for capturing quality measure information on each of the assigned beneficiaries.

As specified in section IV.F.(b).(2).(B). of this proposed rule, we propose to change the definition of the group practices to those practices consisting of 25 or more eligible professionals. In 2011, to distinguish the criteria in GPRO I and II for satisfactory reporting between small vs. large groups, we established different reporting criteria dependent on the group's size. Although we are consolidating the GPRO for 2012, we still recognize the need to equalize the reporting burden by establishing different reporting criteria for small vs. large groups. Therefore, we propose to establish the following two criteria for the satisfactory reporting of Physician Quality Reporting System quality measures under the 2012 GPRO, based on the size of the group practice:

• For group practices comprised of 25–99 eligible professionals participating in the GPRO, we propose that the group practice must report on all GPRO measures included in the web interface (listed in Table 56 of this proposed rule). During the submission period, the group practice will need to access the web interface and populate the data fields necessary for capturing quality measure information on each of the assigned beneficiaries up to 218 beneficiaries (with an over-sample of 327 beneficiaries) for each disease

module and preventive care measure. We further propose that if the pool of eligible assigned beneficiaries for any disease module or preventive care measure is less than 218, then the group practice would need to populate the remaining data files for 100 percent of eligible assigned beneficiaries for that disease module or preventive care measure. For each disease module or preventive care measure, we propose that the group practice must report information on the assigned patients in the order in which they appear in the group's sample (that is, consecutively). We propose these criteria because they mirror the criteria for CMS' Medicare Care Management Performance (MCMP) demonstration. In determining the appropriate reporting criteria for group practices comprised of 25–99 eligible professionals, we sought to align the criteria for satisfactory reporting under the Physician Quality Reporting System with CMS' MCMP demonstration, which uses small to medium-sized group practices to analyze data aimed at improving the quality of care for beneficiaries with chronic conditions. We have an interest in aligning the reporting criteria for these two programs particularly as the MCMP demonstration also required its participants to report on measures similar to the PGP demonstration and using the same data collection vehicle. However, the statistical sampling methodology used in the MCMP demonstration also took into account that the group practices that participated in this demonstration were significantly smaller than those that participate in the PGP demonstration.

- For group practices comprised of 100 or more eligible professionals, we propose that the group practices must report on all Physician Quality Reporting System GPRO quality measures. During the submission period, the group practice would need to populate the remaining data fields in the web interface necessary for capturing quality measure information on each of the assigned beneficiaries up to 411 beneficiaries (with an over-sample of 616 beneficiaries) for each disease module and preventive care measure. We further propose that if the pool of eligible assigned beneficiaries for any disease module or preventive care measure is less than 411, then the group practice must populate the remaining data fields for 100 percent of eligible assigned beneficiaries for that disease module or preventive care measure. For each disease module or preventive care measure, we propose that the group practice must report information on the assigned patients in the order in which they appear in the group's sample (that is, consecutively).

Furthermore, although we are requiring that the group practices participating as GPROs report on a certain number of consecutive patients, such as either 218 or 411 beneficiaries depending on the group's size, we propose to allow the ''skipping'' of patients for valid reasons, such as a beneficiary's medical records not being found or not being able to confirm a diagnosis. However, excessive skipping of patients may cause us to question the accuracy or validity of the data being reported to us by the group practices. Due to the variance in group patterns, measures, and disease modules, however, it is difficult to establish a ''skip threshold'' for the satisfactory reporting of GPRO measures. Therefore, it is our intent to examine each group practice's skip patterns. We may request the group to provide additional information to help explain or support the skips to help better inform us on what levels of skipping could potentially be considered excessive skipping in a future year.

In determining the appropriate reporting criteria for group practices comprised of 100 or more eligible professionals, we sought to use the same criteria as we finalized in the 2011 MPFS Final Rule with comment period for GPRO I (75 FR 73506) because group practices are already familiar with this reporting process. We hope that establishing the same process for reporting under the GPRO as proposed in prior years will provide a likelier chance for meeting the criteria for satisfactory reporting under the GPRO. In addition, we sought to align the criteria for satisfactory reporting under the Physician Quality Reporting System with CMS' Physician Group Practice (PGP) demonstration, which collects data from large group practices in an effort to coordinate the overall care delivered to Medicare patients.

As we discussed previously with our proposed definition of group practice, we allow for fluctuation of the group practice's size throughout the reporting period, provided that the group size contains at least 25 eligible professionals, which is the proposed minimum group practice size for participation in the Physician Quality Reporting System GPRO. However, as we established in 2011, for purposes of determining which reporting criteria the group must satisfy, a group practice's size will be the size of the group at the time the group's participation is approved by CMS (75 FR 73504). For example, if a group practice is comprised of 100 eligible professionals at the time it self-nominates for participation as a GPRO in 2012, and the group practice's size then drops to 99 eligible professionals at the time the group practice's participation is approved by CMS, the group practice would need to meet the proposed reporting criteria for a group size of 99.

Table 28 summarizes the proposed criteria for the satisfactory reporting of data on quality measures by group practice under the proposed 2012 Physician Quality Reporting GPRO. We propose that group practices participating in the 2012 Physician Quality Reporting System GPRO, regardless of size, would be required to report on all of the proposed measures listed in Table 56 of this proposed rule. These quality measures are grouped into preventive care measures and five disease modules: heart failure, diabetes, coronary artery disease, hypertension, and chronic obstructive pulmonary disease (COPD).

TABLE 28—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING FOR GROUP PRACTICES PARTICIPATING IN THE PHYSICIAN QUALITY REPORTING SYSTEM GROUP PRACTICE REPORTING OPTION (GPRO)

Group practice size	Reporting mechanism	Reporting criteria	Reporting period
25–99 Eligible Professionals	A submission web interface provided by CMS.	• 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 (with an over-sample of 327) for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100% of assigned beneficiaries.	January 1, 2012–December 31, 2012.

TABLE 28—PROPOSED 2012 CRITERIA FOR SATISFACTORY REPORTING FOR GROUP PRACTICES PARTICIPATING IN THE PHYSICIAN QUALITY REPORTING SYSTEM GROUP PRACTICE REPORTING OPTION (GPRO)—Continued

Group practice size	Reporting mechanism	Reporting criteria	Reporting period
100+ Eligible Professionals ..	A submission web interface provided by CMS.	• 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 (with an over-sample of 616) for each disease module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100% of assigned beneficiaries.	January 1, 2012–December 31, 2012.

We intend to post the final 2012 Physician Quality Reporting System GPRO participation requirements for group practices, including instructions for submitting the self-nomination statement and other requested information, on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.gov/PQRS* by November 15, 2011 or shortly thereafter.

The Physician Quality Reporting System GPRO web interface will be updated as needed to include the 2012 Physician Quality Reporting System GPRO measures (i.e. to eliminate measures that have been retired as well as add additional measures that will be finalized for 2012). We believe that use of the GPRO web interface allows group practices the opportunity to calculate their own performance rates on the quality measures.

We intend to provide the selected physician groups with access to this pre-populated database by no later than the first quarter of 2013. For purposes of pre-populating this GPRO web interface, we propose to assign beneficiaries to each group practice using a patient assignment methodology modeled after the patient assignment methodology used in the PGP & MCMP demonstrations. Based on our desire to model the Physician Quality Reporting System GPRO after the PGP & MCMP demonstrations, we will also consider incorporating any methodologies used in the PGP demonstration prior to January 1, 2012 to the 2012 Physician Quality Reporting System. We propose using Medicare Part B claims data for dates of service on or after January 1, 2011 and submitted and processed by approximately October 31, 2011 to assign Medicare beneficiaries to each group practice. Assigned beneficiaries would be limited to those Medicare Part B FFS beneficiaries with Medicare Parts A and B claims for whom Medicare is the primary payer. Assigned beneficiaries would not include Medicare Advantage enrollees. A beneficiary would be assigned to the group practice that provides 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 would be eliminated from the group practice's assigned patient sample for purposes of the 2012 Physician Quality Reporting System GPRO. We would pre-populate the GPRO web interface with the assigned beneficiaries' demographic and utilization information based on their Medicare claims data.

We invite public comment on the proposed requirements for satisfactory reporting via the Physician Quality Reporting System GPRO reporting option.

f. 2012 Physician Quality Reporting System Measures

(1) Statutory Requirements for the Selection of Proposed 2012 Physician Quality Reporting System Measures

Under section 1848(k)(2)(C)(i) of the Act, the Physician Quality Reporting System 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 proposed 2012 Physician Quality Reporting System quality measure would need to be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each 2012 Physician Quality Reporting System 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 with respect to 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 Physician Quality Reporting System.

(2) Other Considerations for the Selection of Proposed 2012 Physician Quality Reporting System Measures

In addition to reviewing the 2011 Physician Quality Reporting System measures for purposes of developing the proposed 2012 Physician Quality Reporting System measures, we reviewed and considered measure suggestions for the 2012 Physician Quality Reporting System.

With respect to the selection of new measures, we applied the following

considerations, which include many of the same considerations applied to the selection of 2009, 2010 and 2011 Physician Quality Reporting System quality measures proposed for inclusion in the 2012 Physician Quality Reporting System quality measure set previously described:

• 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. These current and long term priority topics include the following: Prevention; chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other conditions; improved care coordination; improved outcomes; improved efficiency; improved patient and family experience of care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable HIT.

++ Measures that are included in, or facilitate alignment with, other Medicare, Medicaid, and CHIP programs in furtherance of overarching healthcare goals.

++ NQF Endorsement.

++ Measures must be NQF-endorsed by August 15, 2011, in order to be considered for inclusion in the 2012 Physician Quality Reporting System quality measure set except as provided under section 1848(k)(2)(C)(ii) of the Act.

++ 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).

• Address Gaps in the Physician Quality Reporting System Measure Set.

++ Measures that increase the scope of applicability of the Physician Quality Reporting System measures to services furnished to Medicare beneficiaries and expand opportunities for eligible professionals to participate in the Physician Quality Reporting System.

• Measures of various aspects of clinical quality including outcome measures, where appropriate and feasible, process measures, structural measures, efficiency measures, and measures of patient experience of care.

Other considerations that we applied to the selection of proposed measures for 2012, regardless of whether the measure was a 2011 Physician Quality Reporting System measure or not, were—

• Measures that are functional, which is to say measures that can be technically implemented within the capacity of the CMS infrastructure for data collection, analysis, and calculation of reporting and performance rates.

• Measures that address gaps in the quality of care delivered to Medicare beneficiaries;

• Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal);

• Measures involving care coordination;

• Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.)

• Measures conducive to leveraging capabilities of an electronic health record (EHR)

• Measures whose detailed specifications will be completed and ready for implementation in the 2012 Physician Quality Reporting System

• 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.

In the 2012 Physician Quality Reporting System, as in the 2011 Physician Quality Reporting System, for some measures that are useful, but where data submission is not feasible through all otherwise available Physician Quality Reporting System reporting mechanisms, we are proposing that a measure may be included for reporting solely through specific reporting mechanism(s) in which its submission is feasible.

As discussed previously, section 1848(k)(2)(D) of the Act requires that the public have the opportunity to provide input during the selection of measures. We also are required by other applicable statutes to provide opportunity for public comment on provisions of policy or regulation that are established via notice and comment rulemaking. Measures that are not included in the proposed rule for inclusion in the 2012 Physician Quality Reporting System that are recommended to us via comments on the proposed rule have not been placed before the public to comment on the selection of those measures within the rulemaking process. Even when measures have been published in the **Federal Register**, but in other contexts and not specifically proposed as Physician Quality Reporting System measures, such publication does not provide true opportunity for public comment on those measures' potential inclusion in the Physician Quality Reporting System. Thus, such additional measures recommended for selection for the 2012 Physician Quality Reporting System via comments on the CY 2012 PFS proposed rule cannot be included in the 2012 measure set. As such, while we welcome all constructive comments and suggestions, and may consider such recommended measures for inclusion in future measure sets for the Physician Quality Reporting System and other programs to which such measures may be relevant, we are not able to consider such additional measures for inclusion in the final 2012 Physician Quality Reporting System measure set.

In addition, as in prior years, we again note that we do not use notice and comment rulemaking as a means to update or modify measure specifications. Quality measures that have completed the consensus process have a designated party (usually, the measure developer/owner) who has accepted responsibility for maintaining the measure. In general, it is the role of the measure owner, developer, or maintainer to make changes to a measure. Therefore, comments requesting changes to a specific proposed Physician Quality Reporting System measure's title, definition, and detailed specifications or coding should be directed to the measure developer identified in Tables 29 through 55. Contact information for the 2011 Physician Quality Reporting System measure developers is listed in the ''2011 Physician Quality Reporting System Quality Measures List,'' which is available on the CMS Web site at *http://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage.*

However, we stress that inclusion of measures that are not NQF endorsed or AQA adopted is an exception to the requirement under section 1848(k)(2)(C)(i) of the Act that measures be endorsed by the NQF. We may exercise this exception authority in a specified area or medical topic for which a feasible and practical measure has not been endorsed by NQF, so long as due consideration is given to measures that have been endorsed by the NQF.

Based on the criteria previously discussed, we propose to include the individual measures listed in Tables 29 through 31 in the 2012 Physician Quality Reporting System individual quality measure set. We believe that each measure we are proposing for reporting under the 2012 Physician Quality Reporting System meets at least one criterion for the selection of Physician Quality Reporting System measures described previously. We are also proposing to include 24 measures

groups in the 2012 Physician Quality Reporting System quality measure set, which are listed in Tables 29 through 31. The individual measures selected for the 2012 Physician Quality Reporting System can be categorized as follows—

- Proposed 2012 Physician Quality Reporting System Core Measures Available for Either Claims, Registry, and/or EHR-Based Reporting;
- Proposed 2012 Physician Quality Reporting System Individual Quality Measures Available for Either Claims-based Reporting and/or Registry-based Reporting; AND
- Proposed 2012 Physician Quality Reporting System Measures Available for EHR-Based Reporting.

Please note that some individual measures we are proposing in Tables 29 through 31 for reporting for the 2012 Physician Quality Reporting System may be available for reporting in other CMS programs, such as the Medicare and Medicaid EHR Incentive Program as well as the Medicare Shared Savings Program. We note that measure titles, in some instances, may vary from program to program. If an eligible professional intends to report the same measures for multiple CMS programs, it is important to check the full measure specifications, NQF measure number (if applicable), as well as any other identifying measure features to determine whether the measures are the same. We invite comments on our proposed approach in selecting measures.

(3) Proposed 2012 Physician Quality Reporting System Individual Measures

This section focuses on the proposed 2012 Physician Quality Reporting System Individual Measures available for reporting via claims and/or registry. For the proposed 2012 Physician Quality Reporting System measures that were selected for reporting in 2011, please note that detailed measure specifications, including the measure's title, for the proposed 2012 individual Physician Quality Reporting System quality measures may have been updated or modified during the NQF endorsement process or for other reasons prior to 2012. The 2012 Physician Quality Reporting System quality measure specifications for any given individual quality measure may, therefore, be different from specifications for the same quality measure used in prior years. Specifications for all 2012 individual Physician Quality Reporting System quality measures, whether or not included in the 2011 Physician Quality Reporting System program, must be obtained from the specifications document for 2012 individual Physician Quality Reporting System quality measures, which will be available on the Physician Quality Reporting System section of the CMS Web site on or before December 31, 2011.

(A) Proposed 2012 Physician Quality Reporting System Core Measures Available for Claims, Registry, and/or EHR-Based Reporting

The prevention of cardiovascular conditions is a top priority for CMS. Therefore, in an effort to encourage eligible professionals to monitor their performance with respect to the prevention of cardiovascular conditions, we propose to adopt a Physician Quality Reporting System set of core measures for CY 2012, which are specified later in this section in Table 29, which focuses on the prevention of cardiovascular conditions.

While we encourage reporting of these measures by all eligible professionals, as previously discussed in section IV.F.1.f. of this proposed rule, we are proposing that only certain specialties be required to report on the proposed 2012 Physician Quality Reporting System core measures.

TABLE 29—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM CORE MEASURES AVAILABLE FOR EITHER CLAIMS, REGISTRY, AND/OR EHR-BASED REPORTING

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.	0068	NCQA	Claims, Registry, EHR.
236	Controlling High Blood Pressure	0018	NCQA	Claims, Registry, EHR.
2	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus.	0064	NCQA	Claims, Registry, EHR.
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention.	0028	AMA-PCPI	Claims, Registry, EHR.
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100.	0075	NCQA	Claims, Registry, EHR.
TBD	Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years.	N/A	CMS	Claims, Registry, EHR.
TBD	Preventative Care: Cholesterol-LDL test performed	N/A	CMS	EHR.

We invite public comment on the proposed 2012 Physician Quality Reporting System core measures.

(B) Proposed 2012 Physician Quality Reporting System Individual Measures for Claims and Registry Reporting

For 2012, we propose to retain all measures currently used in the 2011 Physician Quality Reporting System. We believe these 2011 Physician Quality Reporting System measures meet the statutory considerations as well as other factors we used in determining which measures to include for reporting under the 2012 Physician Quality Reporting System. The retention of these measures also promotes program consistency. These proposed measures include 55 registry-only measures currently used in the 2011 Physician Quality Reporting System, and 144 individual quality measures for either claims-based reporting or registry-based reporting (75 FR 40186 through 40190 and 52489 through 52490). These proposed measures do not include any measures that are proposed to be included as part of the Back Pain measures group. For 2012, we propose that any 2012 Physician Quality Reporting System measures that are included in the Back Pain measures group would not be reportable as individual measures through claims-based reporting or registry-based reporting.

In 2011, Physician Quality Reporting System measure # 197 was titled ''Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL–Cholesterol''. For 2012, we are changing the title of measure # 197 to ''Coronary Artery Disease: Lipid Control'', because the measure owner, AMA–PCPI, has changed the title of the measure. Aside from the title change, measure # 197's NQF number as well as its NQF-endorsement status has not changed. However, as noted previously, please check the measure specifications for measure # 197, as the specifications on how to report on measure # 197 for the 2012 Physician Quality Reporting System may change from 2011.

In addition, we propose the 26 new individual measures below for inclusion in the 2012 Physician Quality Reporting System in order to provide eligible professionals with more Physician Quality Reporting System quality measures on which they can select from to report. The following 2 proposed measures are NQF-endorsed:

- Anticoagulation for Acute Pulmonary Embolus Patients.
- Pregnancy Test for Female Abdominal Pain Patients.

The remaining 24 measures are either pending NQF endorsement or would have to be adopted under the exception to NQF endorsement provided under section 1848(k)(2)(C)(ii) of the Act. In selecting these measures, we took into account other considerations listed in section IV.F.1.(f).(2). of this proposed rule. Specifically, we are proposing the following measures because the measures impact chronic conditions:

- 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.
- Hypertension: Blood Pressure Control.

We are proposing the following measures because these measures involve care coordination:

- Coronary Artery Disease (CAD): Symptom Management.

We are proposing the following measures because these measures are applicable across care settings:

- 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.
- Cardiac Rehabilitation Patient Referral From an Outpatient Setting.

We are proposing the following measures because we believe the measures address gaps in the Physician Quality Reporting System measure set:

- Barrett's Esophagus.
- Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain.
- Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure.
- Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR).
- Referral for Otology Evaluation for Patients with Acute or Chronic Dizziness.
- Image Confirmation of Successful Excision of Image—Localized Breast Lesion.
- Improvement in Patient's Visual Function within 90-Days Following Cataract Surgery.
- Patient Satisfaction within 90-Days Following Cataract Surgery.

We are proposing the following measures because we believe the measures increase the scope of applicability of the Physician Quality Reporting System measures to services furnished to Medicare beneficiaries and expand opportunities for eligible professionals to participate in the Physician Quality Reporting System:

- Radical Prostatectomy Pathology Reporting.
- Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients.

We are proposing the following measures because the measures are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.

- Statin Therapy at Discharge after Lower Extremity Bypass (LEB).
- Rate of Open AAA Repair without Major Complications (discharged to home no later than post-operative day #7).
- Rate of EVAR without Major Complications (discharged to home no later than POD #2).
- Rate of Carotid Endarterectomy for Asymptomatic Patients, without Major Complications (discharged to home no later than post-operative day #2).

We are proposing the following measures because the measures have a high impact on health care:

- Preoperative Diagnosis of Breast Cancer.
- Sentinel Lymph Node Biopsy for Invasive Breast Cancer.
- Biopsy Follow-up.

We believe that the addition of Physician Quality Reporting System quality measures will encourage eligible professionals to participate in the Physician Quality Reporting System, as there are more measures that may be applicable to eligible professionals.

Of these measures, 13 would be reportable via registry-only. The remaining 13 measures would be available for claims and registry reporting. Although we are proposing to designate certain measures as registry-only measures, we cannot guarantee that there will be a registry qualified to submit each registry-only measure for 2012. We rely on registries to self-nominate and identify the measures for which they would like to be qualified to submit quality measures results and numerator and denominator data on quality measures. If no registry self-nominates to submit measure results and numerator and denominator data on a particular measure for 2012, then an eligible professional would not be able to report that particular measure.

Table 30 identifies the list of measures we propose to include for claims and/or registry-based reporting in the 2012 Physician Quality Reporting System. The proposed 2012 Physician Quality Reporting System individual measures for either claims-based reporting or registry-based reporting are listed by their Physician Quality Reporting System Measure Number (to the extent the measure is part of the 2011 Physician Quality Reporting System measure set) and Title in Table 30, along with the name of the measure's developer/owner and NQF measure number, if applicable. The Physician Quality Reporting System Measure Number is a unique identifier assigned by CMS to all measures in the Physician Quality Reporting System measure set. Once a Physician Quality Reporting System Measure Number is assigned to a measure, it will not be used again to identify a different measure, even if the original measure to which the number was assigned is subsequently retired from the Physician Quality Reporting System measure set. A description of the measures listed in Table 30 can be found in the ''2011 Physician Quality Reporting System Quality Measures List,'' which is available on the Measures and Codes page of the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/PQRS* to the extent the measure is part of the 2011 Physician Quality Reporting System measure set. New measures that we are proposing to add to the Physician Quality Reporting System measure set for 2012 are designated with a Physician Quality Reporting System Measure Number of ''TBD.''

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.	0059	NCQA	Claims, Registry.
2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus.	0064	NCQA	Claims, Registry.
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.	0061	NCQA	Claims, Registry.
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0081	AMA–PCPI	Registry.
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.	0067	AMA–PCPI	Claims, Registry.
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).	0070	AMA–PCPI	Registry.
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0083	AMA–PCPI	Registry.
9	Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD.	0105	NCQA	Claims, Registry.
10	Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports.	00246	AMA–PCPI/NCQA	Claims, Registry.
12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation.	0086	AMA–PCPI	Claims, Registry.
14	Age-Related Macular Degeneration (AMD): Dilated Macular Examination.	0087	AMA–PCPI/NCQA	Claims, Registry.
18	Diabetic Retinopathy	0088	AMA–PCPI	Claims, Registry.
19	Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care.	0089	AMA–PCPI	Claims, Registry.
20	Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician.	0270	AMA–PCPI/NCQA	Claims, Registry.
21	Perioperative Care: Selection of Prophylactic Antibiotic	0268	AMA–PCPI/NCQA	Claims, Registry.
22	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures).	0271	AMA–PCPI/NCQA	Claims, Registry.
23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).	0239	AMA–PCPI/NCQA	Claims, Registry.
24	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.	0045	AMA–PCPI/NCQA	Claims, Registry.
28	Aspirin at Arrival for Acute Myocardial Infarction (AMI)	0092	AMA–PCPI/NCQA	Claims, Registry.
30	Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics.	0270	AMA–PCPI/NCQA	Claims, Registry.
31	Stroke and Stroke Rehabilitation: Deep Vein Thrombosis Prophylaxis (DVT) for Ischemic Stroke or Intracranial Hemorrhage.	0240	AMA–PCPI/NCQA	Claims, Registry.
32	Stroke and Stroke Rehabilitation: Discharged on Antiplatelet Therapy.	0325	AMA–PCPI/NCQA	Claims, Registry.
33	Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge.	0241	AMA–PCPI/NCQA	Registry.
35	Stroke and Stroke Rehabilitation: Screening for Dysphagia.	0243	AMA–PCPI/NCQA	Claims, Registry.
36	Stroke and Stroke Rehabilitation: Consideration of Rehabilitation Services.	0244	AMA–PCPI/NCQA	Claims, Registry.
39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.	0046	AMA–PCPI/NCQA	Claims, Registry.
40	Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.	0045	AMA–PCPI/NCQA	Claims, Registry.
41	Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older.	0049	AMA–PCPI/NCQA	Claims, Registry.
43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery.	0516	STS	Claims, Registry.
44	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery.	0235	STS	Claims, Registry.
45	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures).	0637	AMA–PCPI/NCQA	Claims, Registry.

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING—Continued

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
46	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.	0097	AMA–PCPI/NCQA	Claims, Registry.
47	Advance Care Plan	0326	AMA–PCPI/NCQA	Claims, Registry.
48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.	0098	AMA–PCPI/NCQA	Claims, Registry.
49	Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older.	0099	AMA–PCPI/NCQA	Claims, Registry.
50	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older.	0100	AMA–PCPI/NCQA	Claims, Registry.
51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.	0091	AMA–PCPI	Claims, Registry.
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.	0102	AMA–PCPI	Claims, Registry.
53	Asthma: Pharmacologic Therapy	0047	AMA–PCPI	Claims, Registry.
54	12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain.	0090	AMA–PCPI/NCQA	Claims, Registry.
55	12-Lead Electrocardiogram (ECG) Performed for Syncope.	0093	AMA–PCPI/NCQA	Claims, Registry.
56	Community-Acquired Pneumonia (CAP): Vital Signs	0232	AMA–PCPI/NCQA	Claims, Registry.
57	Community-Acquired Pneumonia (CAP): Assessment of Oxygen Saturation.	0094	AMA–PCPI/NCQA	Claims, Registry.
58	Community-Acquired Pneumonia (CAP): Assessment of Mental Status.	0234	AMA–PCPI/NCQA	Claims, Registry.
59	Community-Acquired Pneumonia (CAP): Empiric Antibiotic.	0096	AMA–PCPI/NCQA	Claims, Registry.
64	Asthma: Asthma Assessment	0001	AMA–PCPI	Claims, Registry.
65	Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use.	0069	NCQA	Claims, Registry.
66	Appropriate Testing for Children with Pharyngitis	0002	NCQA	Claims, Registry.
67	Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow.	0377	AMA–PCPI/ASH	Claims, Registry.
68	Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy.	0378	AMA–PCPI/ASH	Claims, Registry.
69	Multiple Myeloma: Treatment with Bisphosphonates	0380	AMA–PCPI/ASH	Claims, Registry.
70	Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry.	0379	AMA–PCPI/ASH	Claims, Registry.
71	Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.	0387	AMA–PCPI/ASCO/NCCN	Claims, Registry.
72	Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients.	0385	AMA–PCPI/ASCO/NCCN	Claims, Registry.
76	Prevention of Catheter-Related Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol.	0464	AMA–PCPI	Claims, Registry.
79	End Stage Renal Disease (ESRD): Influenza Immunization in Patients with ESRD.	0227	AMA–PCPI	Claims, Registry.
81	End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients.	0323	AMA–PCPI	Registry.
82	End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis.	0321	AMA–PCPI	Registry.
83	Hepatitis C: Testing for Chronic Hepatitis C—Confirmation of Hepatitis C Viremia.	0393	AMA–PCPI	Registry.
84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment.	0395	AMA–PCPI	Claims, Registry.
85	Hepatitis C: HCV Genotype Testing Prior to Treatment	0396	AMA–PCPI	Claims, Registry.
86	Hepatitis C: Antiviral Treatment Prescribed	0397	AMA–PCPI	Claims, Registry.
87	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment.	0398	AMA–PCPI	Claims, Registry.
89	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption.	0401	AMA–PCPI	Claims, Registry.
90	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy.	0394	AMA–PCPI	Claims, Registry.
91	Acute Otitis Externa (AOE): Topical Therapy	0653	AMA–PCPI	Claims, Registry.
92	Acute Otitis Externa (AOE): Pain Assessment	N/A	AMA–PCPI	Claims, Registry.

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING—Continued

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
93	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy—Avoidance of Inappropriate Use.	0654	AMA–PCPI	Claims, Registry.
94	Otitis Media with Effusion (OME): Diagnostic Evaluation—Assessment of Tympanic Membrane Mobility.	N/A	AMA–PCPI	Claims, Registry.
99	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.	0391	AMA–PCPI/CAP	Claims, Registry.
100	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade.	0392	AMA–PCPI/CAP	Claims, Registry.
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients.	0389	AMA–PCPI	Claims, Registry.
104	Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Prostate Cancer Patients.	0390	AMA–PCPI	Claims, Registry.
105	Prostate Cancer: Three-Dimensional (3D) Radiotherapy	0388	AMA–PCPI	Claims, Registry.
106	Major Depressive Disorder (MDD): Diagnostic Evaluation.	0103	AMA–PCPI	Claims, Registry.
107	Major Depressive Disorder (MDD): Suicide Risk Assessment.	0104	AMA–PCPI	Claims, Registry.
108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy.	0054	NCQA	Claims, Registry.
109	Osteoarthritis (OA): Function and Pain Assessment	0050	AMA–PCPI	Claims, Registry.
110	Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old.	0041	AMA–PCPI	Claims, Registry.
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.	0043	NCQA	Claims, Registry.
112	Preventive Care and Screening: Screening Mammography.	0031	NCQA	Claims, Registry.
113	Preventive Care and Screening: Colorectal Cancer Screening.	0034	NCQA	Claims, Registry.
116	Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use.	0058	NCQA	Claims, Registry.
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	NCQA	Claims, Registry.
118	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).	0066	AMA–PCPI	Registry.
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.	0062	NCQA	Claims, Registry.
121	Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile).	N/A	AMA–PCPI	Claims, Registry.
122	Chronic Kidney Disease (CKD): Blood Pressure Management.	AQA adopted	AMA–PCPI	Claims, Registry.
123	Chronic Kidney Disease (CKD): Plan of Care—Elevated Hemoglobin for Patients Receiving Erythropoiesis-Stimulating Agents (ESA).	AQA adopted	AMA–PCPI	Claims, Registry.
124	Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR).	0488	CMS/QIP	Claims, Registry.
126	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy—Neurological Evaluation.	0417	APMA	Claims, Registry.
127	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear.	0416	APMA	Claims, Registry.
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.	0421	CMS/QIP	Claims, Registry.
130	Documentation of Current Medications in the Medical Record.	0419	CMS/QIP	Claims, Registry.
131	Pain Assessment Prior to Initiation of Patient Therapy and Follow-Up.	0420	CMS/QIP	Claims, Registry.
134	Screening for Clinical Depression and Follow-Up Plan	0418	CMS/QIP	Claims, Registry.
135	Chronic Kidney Disease (CKD): Influenza Immunization	AQA adopted	AMA–PCPI	Claims, Registry.
137	Melanoma: Continuity of Care—Recall System	0650	AMA–PCPI/NCQA	Registry.
138	Melanoma: Coordination of Care	0561	AMA–PCPI/NCQA	Registry.
140	Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement.	0566	AMA–PCPI/NCQA	Claims, Registry.

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING—Continued

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
141	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care.	0563	AMA–PCPI/NCQA	Claims, Registry.
142	Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications.	0051	AMA–PCPI	Claims, Registry.
143	Oncology: Medical and Radiation—Pain Intensity Quantified.	0384	AMA–PCPI	Registry.
144	Oncology: Medical and Radiation—Plan of Care for Pain.	0383	AMA–PCPI	Registry.
145	Radiology: Exposure Time Reported for Procedures Using Fluoroscopy.	0510	AMA–PCPI/NCQA	Claims, Registry.
146	Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening.	0508	AMA–PCPI/NCQA	Claims, Registry.
147	Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy.	0511	AMA–PCPI	Claims, Registry.
153	Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula.	AQA adopted	AMA–PCPI	Claims, Registry.
154	Falls: Risk Assessment	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
155	Falls: Plan of Care	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
156	Oncology: Radiation Dose Limits to Normal Tissues	0382	AMA–PCPI	Claims, Registry.
157	Thoracic Surgery: Recording of Clinical Stage for Lung Cancer and Esophageal Cancer Resection.	0455	STS	Claims, Registry.
158	Carotid Endarterectomy: Use of Patch During Conventional Carotid Endarterectomy.	0466	SVS	Claims, Registry.
159	HIV/AIDS: CD4+ Cell Count or CD4+ Percentage	0404	AMA–PCPI/NCQA	Registry.
160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis.	0405	AMA–PCPI/NCQA	Registry.
161	HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy.	0406	AMA–PCPI/NCQA	Registry.
162	HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy.	0407	AMA–PCPI/NCQA	Registry.
163	Diabetes Mellitus: Foot Exam	0056	NCQA	Claims, Registry.
164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Ventilation).	0129	STS	Registry.
165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate.	0130	STS	Registry.
166	Coronary Artery Bypass Graft (CABG): Stroke/Cerebrovascular Accident (CVA).	0131	STS	Registry.
167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Insufficiency.	0114	STS	Registry.
168	Coronary Artery Bypass Graft (CABG): Surgical Re-exploration.	0115	STS	Registry.
169	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge.	0237	STS	Registry.
170	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge.	0238	STS	Registry.
171	Coronary Artery Bypass Graft (CABG): Lipid Management and Counseling.	0118	STS	Registry.
172	Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula.	0259	SVS	Claims, Registry.
173	Preventive Care and Screening: Unhealthy Alcohol Use—Screening.	AQA adopted	AMA–PCPI	Claims, Registry.
175	Pediatric End Stage Renal Disease (ESRD): Influenza Immunization.	AQA adopted	AMA–PCPI	Claims, Registry.
176	Rheumatoid Arthritis (RA): Tuberculosis Screening	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity.	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
178	Rheumatoid Arthritis (RA): Functional Status Assessment.	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis.	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
180	Rheumatoid Arthritis (RA): Glucocorticoid Management	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
181	Elder Maltreatment Screen and Follow-Up Plan	AQA adopted	CMS/QIP	Claims, Registry.
182	Functional Outcome Assessment in Chiropractic Care	AQA adopted	CMS/QIP	Claims, Registry.

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING—Continued

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
183	Hepatitis C: Hepatitis A Vaccination in Patients with HCV.	0399	AMA–PCPI	Claims, Registry.
184	Hepatitis C: Hepatitis B Vaccination in Patients with HCV.	0400	AMA–PCPI	Claims, Registry.
185	Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.	0659	AMA–PCPI/NCQA	Claims, Registry.
186	Wound Care: Use of Compression System in Patients with Venous Ulcers.	AQA adopted	AMA–PCPI/NCQA	Claims, Registry.
187	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	0437	AHA/ASA/TJC	Registry.
188	Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear.	N/A	AQC	Claims, Registry.
189	Referral for Otologic Evaluation for Patients with History of Active Drainage From the Ear Within the Previous 90 Days.	N/A	AQC	Claims, Registry.
190	Referral for Otologic Evaluation for Patients with a History of Sudden or Rapidly Progressive Hearing Loss.	N/A	AQC	Claims, Registry.
191	Cataracts: 20/40 or Better Visual Acuity Within 90 Days Following Cataract Surgery.	0565	AMA–PCPI/NCQA	Registry.
192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures.	0564	AMA–PCPI/NCQA	Registry.
193	Perioperative Temperature Management	0454	AMA–PCPI	Claims, Registry.
194	Oncology: Cancer Stage Documented	0386	AMA–PCPI/ASCO	Claims, Registry.
195	Radiology: Stenosis Measurement in Carotid Imaging Studies.	0507	AMA–PCPI/NCQA	Claims, Registry.
196	Coronary Artery Disease (CAD): Symptom and Activity Assessment.	0065	AMA–PCPI	Registry.
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA–PCPI	Registry.
198	Heart Failure: Left Ventricular Function (LVF) Assessment.	0079	AMA–PCPI	Registry.
199	Heart Failure: Patient Education	0082	AMA–PCPI	Registry.
200	Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation.	0084	AMA–PCPI	Registry.
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control.	0073	NCQA	Claims, Registry.
202	Ischemic Vascular Disease (IVD): Complete Lipid Profile	0075	NCQA	Claims, Registry.
203	Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C) Control.	0075	NCQA	Claims, Registry.
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.	0068	NCQA	Claims, Registry.
205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea.	0409	AMA–PCPI/NCQA	Registry.
206	HIV/AIDS: Screening for High Risk Sexual Behaviors	0413	AMA–PCPI/NCQA	Registry.
207	HIV/AIDS: Screening for Injection Drug Use	0415	AMA–PCPI/NCQA	Registry.
208	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis.	0410	AMA–PCPI/NCQA	Registry.
209	Functional Communication Measure-Spoken Language Comprehension.	0445	ASHA	Registry.
210	Functional Communication Measure-Attention	0449	ASHA	Registry.
211	Functional Communication Measure-Memory	0448	ASHA	Registry.
212	Functional Communication Measure-Motor Speech	0447	ASHA	Registry.
213	Functional Communication Measure-Reading	0446	ASHA	Registry.
214	Functional Communication Measure-Spoken Language Expression.	0444	ASHA	Registry.
215	Functional Communication Measure-Writing	0442	ASHA	Registry.
216	Functional Communication Measure-Swallowing	0443	ASHA	Registry.
217	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments.	0422	FOTO	Registry.
218	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments.	0423	FOTO	Registry.
219	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments.	0424	FOTO	Registry.
220	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments.	0425	FOTO	Registry.

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING—Continued

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
221	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments.	0426	FOTO	Registry.
222	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments.	0427	FOTO	Registry.
223	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments.	0428	FOTO	Registry.
224	Melanoma: Overutilization of Imaging Studies in Stage 0–IA Melanoma.	0562	AMA–PCPI	Registry.
225	Radiology: Reminder System for Mammograms	0509	AMA–PCPI	Claims, Registry.
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	0028	AMA–PCPI	Claims, Registry.
228	Heart Failure (HF): Left Ventricular Function (LVF) Testing.	0079	CMS	Registry.
231	Asthma: Tobacco Use: Screening-Ambulatory Care Setting.	N/A	AMA–PCPI	Claims, Registry.
232	Asthma: Tobacco Use: Intervention-Ambulatory Care Setting.	N/A	AMA–PCPI	Claims, Registry.
233	Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection.	0457	STS	Registry.
234	Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy).	0458	STS	Registry.
235	Hypertension (HTN): Plan of Care	0017	AMA–PCPI	Claims, Registry.
TBD	Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers.	N/A	ASPS–PCPI–NCQA	Claims, Registry.
TBD	Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers.	N/A	ASPS–PCPI–NCQA	Claims, Registry.
TBD	Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence.	AQA adopted	ASPS–PCPI–NCQA	Claims, Registry.
TBD	Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence.	AQA adopted	ASPS–PCPI–NCQA	Claims, Registry.
TBD	Coronary Artery Disease (CAD): Symptom Management	N/A	ASPS–PCPI–NCQA	Registry.
TBD	Cardiac Rehabilitation Patient Referral From an Outpatient Setting.	N/A	ACCF–AHA	Registry.
TBD	Hypertension: Blood Pressure Control	N/A	ACC–AHA–PCPI	Registry.
TBD	Barrett's Esophagus	N/A	CAP	Claims, Registry.
TBD	Radical Prostatectomy Pathology Reporting	N/A	CAP	Claims, Registry.
TBD	Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients.	N/A	College of American Pathologists.	Claims, Registry.
TBD	Anticoagulation for Acute Pulmonary Embolus Patients	0503	ACEP	Claims, Registry.
TBD	Pregnancy Test for Female Abdominal Pain Patients	0502	ACEP	Claims, Registry.
TBD	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain.	N/A	ACEP	Claims, Registry.
TBD	Rh Immunoglobulin (Rhogam) for Rh Negative Pregnant Women at Risk of Fetal Blood Exposure.	N/A	ACEP	Registry.
TBD	Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR).	N/A	SVS	Registry.
TBD	Statin Therapy at Discharge after Lower Extremity Bypass (LEB).	N/A	SVS	Registry.
TBD	Rate of Open AAA Repair without Major Complications (discharged to home no later than post-operative day #7).	N/A	SVS	Registry.
TBD	Rate of EVAR without Major Complications (discharged to home no later than POD #2).	N/A	SVS	Registry.
TBD	Rate of Carotid Endarterectomy for Asymptomatic Patients, without Major Complications (discharged to home no later than post-operative day #2).	N/A	SVS	Registry.
TBD	Referral for Otology Evaluation for Patients with Acute or Chronic Dizziness.	N/A	AQC	Claims, Registry.
TBD	Image Confirmation of Successful Excision of Image-Localized Breast Lesion.	N/A	ASBS	Claims, Registry.
TBD	Preoperative Diagnosis of Breast Cancer	N/A	ASBS	Claims, Registry.

TABLE 30—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM INDIVIDUAL QUALITY MEASURES AVAILABLE FOR EITHER CLAIMS-BASED REPORTING AND/OR REGISTRY-BASED REPORTING—Continued

Physician quality reporting system measure No.	Measure title	NQF measure No.	Measure developer	Reporting mechanism
TBD	Sentinel Lymph Node Biopsy for Invasive Breast Cancer	N/A	ASBS	Registry.
TBD	Biopsy Follow-up	N/A	AAD	Registry.
TBD	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.	N/A	AAO	Registry.
TBD	Patient Satisfaction within 90 Days Following Cataract Surgery.	N/A	AAO	Registry.

(C) Proposed 2012 Measures Available for EHR-Based Reporting

For 2012, we propose to again accept Physician Quality Reporting System data from EHRs for a limited subset of 2012 Physician Quality Reporting System quality measures.

Section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting and EHR Reporting''), as added by section 3002(d) of the Affordable Care Act, requires that by no later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under the Physician Quality Reporting System with reporting requirements under the EHR Incentive Program under section 1848(o) of the Act relating to the meaningful use of EHRs. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which would both demonstrate—

(i) Meaningful use of an EHR for purposes of the Medicare EHR Incentive Program; and

(ii) Quality of care furnished to an individual; and

(B) Such other activities as specified by the Secretary.

To align the Physician Quality Reporting System with the Medicare EHR Incentive Program, we propose to include all clinical quality measures available for reporting under the Medicare EHR Incentive Program (75 FR 44398 through 44408) in the EHR-Based reporting option in the 2012 Physician Quality Reporting System for purposes of reporting data on quality measures under the EHR-reporting option. In 2011, we included 14 of the 44 EHR Incentive Program measures under the 2011 Physician Quality Reporting System EHR reporting mechanism. In order to better align Physician Quality Reporting System measures with those under the EHR Incentive Program, for 2012, we propose to have the rest of the 44 clinical quality measures in the Medicare EHR Incentive Program available for EHR-Based reporting under the 2012 Physician Quality Reporting System.

Furthermore, for 2012, we propose to retain the following 6 additional measures that were available for reporting under the EHR-Based reporting mechanism under the 2011 Physician Quality Reporting System:

- Measure # 39: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older.
- Measure # 47: Advance Care Plan.
- Measure # 48: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.
- Measure # 124: Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR).
- Measure # 173: Preventive Care and Screening: Unhealthy Alcohol Use—Screening.
- Measure # 238: Drugs to be Avoided in the Elderly.

We believe these measures meet the criteria listed previously for inclusion for reporting under the Physician Quality Reporting System.

Table 31 identifies the list of measures we propose to include for EHR-Based reporting under the 2012 Physician Quality Reporting System.

TABLE 31—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM MEASURES AVAILABLE FOR EHR-BASED REPORTING

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
MEASURES THAT ARE ALSO EHR INCENTIVE PROGRAM CORE MEASURES			
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up *	0421	CMS/QIP
237	Hypertension (HTN): Blood Pressure Measurement	0013	AMA–PCPI
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention **	0028	AMA–PCPI
MEASURES THAT ARE ALSO EHR INCENTIVE PROGRAM ALTERNATE CORE MEASURES			
110	Preventative Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old	0041	AMA–PCPI
239	Weight Assessment and Counseling for Children and Adolescents	0024	NCQA
TBD	Childhood Immunization Status	0038	NCQA
MEASURES THAT ARE ALSO EHR INCENTIVE PROGRAM MEASURES			
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus	0059	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus	0064	NCQA
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	NCQA

TABLE 31—PROPOSED 2012 PHYSICIAN QUALITY REPORTING SYSTEM MEASURES AVAILABLE FOR EHR-BASED REPORTING—Continued

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
5	Heart Failure: Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0081	AMA–PCPI
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.	0067	AMA–PCPI
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).	0070	AMA–PCPI
8	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0083	AMA–PCPI
9	Anti-depressant medication management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment.	0105	NCQA
12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation	0086	AMA–PCPI
18	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.	0088	AMA–PCPI
19	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care.	0089	AMA–PCPI
53	Asthma Pharmacologic	0047	AMA–PCPI
64	Asthma Assessment	0001	AMA–PCPI
66	Appropriate Testing for Children with Pharyngitis	0002	NCQA
71	Oncology Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.	0387	AMA–PCPI
72	Oncology Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients	0385	AMA–PCPI
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.	0389	AMA–PCPI
111	Preventive Care and Screening: Screening Mammography	0043	NCQA
112	Preventive Care and Screening: Colorectal Cancer Screening	0031	NCQA
113	Colorectal Cancer Screening	0034	NCQA
114 & 115	Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies.	0027	NCQA
117	Diabetes: Eye Exam	0055	AMA–PCPI
119	Diabetes: Urine Screening	0062	NCQA
163	Diabetes: Foot Exam	0056	NCQA
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA–PCPI
200	Heart Failure: Warfarin Therapy Patients with Atrial Fibrillation	0084	AMA–PCPI
201	Ischemic Vascular Disease (IVD): Blood Pressure Management	0073	NCQA
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	0068	NCQA
TBD	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement.	0004	NCQA
TBD	Prenatal Care: Screening for Human Immunodeficiency Virus (HIV)	0012	AMA–PCPI
TBD	Prenatal Care: Anti-D Immune Globulin	0014	AMA–PCPI
236	Controlling High Blood Pressure	0018	NCQA
TBD	Cervical Cancer Screening	0032	NCQA
TBD	Chlamydia Screening for Women	0033	NCQA
240	Use of Appropriate Medications for Asthma	0036	NCQA
TBD	Low Back Pain: Use of Imaging Studies	0052	NCQA
202 & 203	Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control	0075	NCQA
TBD	Diabetes: Hemoglobin A1c Control (< 8.0%)	0575	NCQA
OTHER PHYSICIAN QUALITY REPORTING SYSTEM EHR MEASURES			
39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older	0046	AMA–PCPI/NCQA
47	Advance Care Plan	0326	AMA–PCPI/NCQA
48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.	0098	AMA–PCPI/NCQA
124	Health Information Technology (HIT): Adoption/Use of Electronic Health Records (EHR).	0488	CMS/QIP
173	Preventive Care and Screening: Unhealthy Alcohol Use—Screening	AQA Adopted	AMA–PCPI
238	Drugs to be Avoided in the Elderly	0022	NCQA

* For the purpose of reporting this measure under the Physician Quality Reporting System, the reporting of this measure will count if at least one of the two parameters does not contain a 0 percent performance rate.

** For the purpose of reporting this measure under the Physician Quality Reporting System, the reporting of this measure will count if at least one of the two pairs does not contain a 0 percent performance rate.

(4) 2012 Physician Quality Reporting System Measures Groups

We propose to retain the following 14 2011 Physician Quality Reporting System measures groups for the 2012 Physician Quality Reporting System: (1) Diabetes Mellitus; (2) CKD; (3) Preventive Care; (4) CABG; (5) Rheumatoid Arthritis; (6) Perioperative Care; (7) Back Pain; (8) CAD; (9) Heart Failure; (10) IVD; (11) Hepatitis C; (12) HIV/AIDS; (13) CAP, and (14) Asthma. For 2012, we propose that the CABG, CAD, Heart Failure, and HIV/AIDS measures groups would continue to be reportable through the registry-based reporting mechanism only, while the remaining Diabetes Mellitus, CKD, Preventive Care, Rheumatoid Arthritis, Perioperative Care, Back Pain, IVD, Hepatitis C, CAP, and Asthma measures groups would continue to be reportable through either claims-based reporting or registry-based reporting for the 2012 Physician Quality Reporting System. We are retaining these measures groups for the 2012 Physician Quality Reporting System particularly because we believe the measures groups reflect the services furnished to beneficiaries by a particular specialty. We also believe that retaining these measures groups will provide consistency from program year to program year.

In addition to the 14 measures groups previously, we propose the following 10 new measures groups for 2012 to provide eligible professionals with more measures groups on which to report:

- Chronic Obstructive Pulmonary Disease (COPD).
- Inflammatory Bowel Disease.
- Sleep Apnea.
- Epilepsy.
- Dementia.
- Parkinson's.
- Elevated Blood Pressure.
- Radiology.
- Cardiovascular Prevention, which contains individual measures from the proposed Physician Quality Reporting System core measure set previously discussed.
- Cataracts.

These are the measures groups that were presented to us for inclusion for reporting under the 2012 Physician Quality Reporting System. Section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that measures be endorsed by the NQF. We may exercise this exception authority in a specified area or medical topic for which a feasible and practical measure has not been endorsed by NQF, so long as due consideration is given to measures that have been endorsed by the NQF. For the measures contained within these measures groups that are not currently NQF-endorsed, we are proposing to exercise this authority due to our interest in all of the proposed 10 measures group's topics. We believe that each of the proposed additional measures groups address gaps in the Physician Quality Reporting System measures groups and will also allow for greater reporting options for individual eligible professionals, thereby increasing participation in the Physician Quality Reporting System.

Finally, as in previous program years, for 2012, we propose that the measures included in any proposed 2012 measures group be reportable either as individual measures or as part of a measures group, except for the Back Pain measures group, which would continue to be reportable only as part of a measures group and not as individual measures in 2012.

As with measures group reporting in prior program years, we propose that each eligible professional electing to report a group of measures for 2012 must report all measures in the group that are applicable to each patient or encounter to which the measures group applies at least up to the minimum number of patients required by the applicable reporting criteria.

The measures proposed for inclusion in each of the 2012 measures groups are identified in Tables 32 through 55 of this proposed rule. Some measures proposed for inclusion in the 2012 measures groups are also 2011 individual Physician Quality Reporting System measures. The title of each such measure is preceded with its Physician Quality Reporting System Measure Number in Tables 32 through 55. As stated previously, the Physician Quality Reporting System Measure Number is a unique identifier assigned by us to all measures in the Physician Quality Reporting System measure set. Once a Physician Quality Reporting System Measure Number is assigned to a measure, it will not be used again, even if the measure is subsequently retired from the Physician Quality Reporting System measure set. Measures that are not preceded by a number (in other words, those preceded by ''TBD'') in Tables 32 through 55 were never part of a Physician Quality Reporting System measure set prior to 2012. A number will be assigned to such measures for 2012.

TABLE 32—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 DIABETES MELLITUS MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus	0059	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus	0064	NCQA
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	NCQA
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	NCQA
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.	0062	NCQA
163	Diabetes Mellitus: Foot Exam	0056	NCQA

TABLE 33—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 CKD MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
121	Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile).	Not applicable	AMA–PCPI
122	Chronic Kidney Disease (CKD): Blood Pressure Management	AQA adopted	AMA–PCPI

TABLE 33—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 CKD MEASURES GROUP—Continued

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
123	Chronic Kidney Disease (CKD): Plan of Care—Elevated Hemoglobin for Patients Receiving Erythropoiesis–Stimulating Agents (ESA).	AQA adopted	AMA–PCPI
153	Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula	AQA adopted	AMA–PCPI

TABLE 34—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 PREVENTATIVE CARE MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older	0046	AMA–PCPI/NCQA
48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older.	0098	AMA–PCPI/NCQA
110	Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old	0041	AMA–PCPI
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.	0043	NCQA
112	Preventive Care and Screening: Screening Mammography	0031	NCQA
113	Preventive Care and Screening: Colorectal Cancer Screening	0034	NCQA
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up	0421	CMS/QIP
173	Preventive Care and Screening: Unhealthy Alcohol Use—Screening	AQA adopted	AMA–PCPI
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA–PCPI

TABLE 35—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 CABG MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery.	0516	STS
44	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery.	0235	STS
164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Ventilation)	0129	STS
165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate	0130	STS
166	Coronary Artery Bypass Graft (CABG): Stroke/Cerebrovascular Accident (CVA)	0131	STS
167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Insufficiency	0114	STS
168	Coronary Artery Bypass Graft (CABG): Surgical Re-exploration	0115	STS
169	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge	0237	STS
170	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge	0238	STS
171	Coronary Artery Bypass Graft (CABG): Lipid Management and Counseling	0118	STS

* This measures group is reportable through registry-based reporting only.

TABLE 36—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 RHEUMATOID ARTHRITIS MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy	0054	NCQA
176	Rheumatoid Arthritis (RA): Tuberculosis Screening	AQA adopted	AMA–PCPI/NCQA
177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity	AQA adopted	AMA–PCPI/NCQA
178	Rheumatoid Arthritis (RA): Functional Status Assessment	AQA adopted	AMA–PCPI/NCQA
179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis	AQA adopted	AMA–PCPI/NCQA
180	Rheumatoid Arthritis (RA): Glucocorticoid Management	AQA adopted	AMA–PCPI/NCQA

TABLE 37—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 PERIOPERATIVE CARE MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF Measure No.	Measure developer
20	Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician	0270	AMA–PCPI/NCQA

TABLE 37—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 PERIOPERATIVE CARE MEASURES GROUP—Continued

Physician quality reporting system No.	Measure title	NQF Measure No.	Measure developer
21	Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin.	0268	AMA–PCPI/NCQA
22	Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures).	0271	AMA–PCPI/NCQA
23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).	0239	AMA–PCPI/NCQA

TABLE 38—PROPOSED MEASURES INCLUDED IN THE 2012 PROPOSED BACK PAIN MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
148	Back Pain: Initial Visit	0322	NCQA
149	Back Pain: Physical Exam	0319	NCQA
150	Back Pain: Advice for Normal Activities	0315	NCQA
151	Back Pain: Advice Against Bed Rest	0313	NCQA

TABLE 39—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 CAD MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.	0067	AMA–PCPI
196	Coronary Artery Disease (CAD): Symptom and Activity Assessment	0065	AMA–PCPI
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA–PCPI
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA–PCPI

* This measures group is reportable through registry-based reporting only.

TABLE 40—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 HEART FAILURE MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0081	AMA–PCPI
8	Heart Failure: Beta–Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0083	AMA–PCPI
198	Heart Failure: Left Ventricular Function (LVF) Assessment	0079	AMA–PCPI
199	Heart Failure: Patient Education	0082	AMA–PCPI
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA–PCPI

* This measures group is reportable through registry-based reporting only.

TABLE 41—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 IVD MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control	0073	NCQA
202	Ischemic Vascular Disease (IVD): Complete Lipid Profile	0075	NCQA
203	Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL–C) Control	0075	NCQA
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	0068	NCQA
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA–PCPI

TABLE 42—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 HEPATITIS C MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment	0395	AMA–PCPI
85	Hepatitis C: HCV Genotype Testing Prior to Treatment	0396	AMA–PCPI
86	Hepatitis C: Antiviral Treatment Prescribed	0397	AMA–PCPI
87	Hepatitis C: HCV Ribonucleic Acid (RNA) Testing at Week 12 of Treatment	0398	AMA–PCPI
89	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption	0401	AMA–PCPI
90	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy	0394	AMA–PCPI
183	Hepatitis C: Hepatitis A Vaccination in Patients with HCV	0399	AMA–PCPI
184	Hepatitis C: Hepatitis B Vaccination in Patients with HCV	0400	AMA–PCPI

TABLE 43—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 HIV/AIDS MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
159	HIV/AIDS: CD4+ Cell Count or CD4+ Percentage	0404	AMA–PCPI/NCQA
160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis	0405	AMA–PCPI/NCQA
161	HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy.	0406	AMA–PCPI/NCQA
162	HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy	0407	AMA–PCPI/NCQA
205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia and Gonorrhea	0409	AMA–PCPI/NCQA
206	HIV/AIDS: Screening for High Risk Sexual Behaviors	0413	AMA–PCPI/NCQA
207	HIV/AIDS: Screening for Injection Drug Use	0415	AMA–PCPI/NCQA
208	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis	0410	AMA–PCPI/NCQA

* This measures group is selected to be reportable through registry-based reporting only.

TABLE 44—PROPOSED MEASURES INCLUDED IN THEPROPOSED 2012 CAP MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
56	Community–Acquired Pneumonia (CAP): Vital Signs	0232	AMA–PCPI/NCQA
57	Community–Acquired Pneumonia (CAP): Assessment of Oxygen Saturation	0094	AMA–PCPI/NCQA
58	Community–Acquired Pneumonia (CAP): Assessment of Mental Status	0234	AMA–PCPI/NCQA
59	Community–Acquired Pneumonia (CAP): Empiric Antibiotic	0096	AMA–PCPI/NCQA

TABLE 45—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 ASTHMA MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
53	Asthma: Pharmacologic Therapy	0047	AMA–PCPI
64	Asthma: Asthma Assessment	0001	AMA–PCPI
231	Asthma: Tobacco Use: Screening—Ambulatory Setting	N/A	AMA–PCPI
232	Asthma: Tobacco Use: Intervention—Ambulatory Screening	N/A	AMA–PCPI

TABLE 46—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 COPD MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
110	Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old	0041	AMA–PCPI
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.	0043	AMA–PCPI
51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation	0091	AMA–PCPI
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy	0102	AMA–PCPI
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA–PCPI

TABLE 47—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 IBD MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Inflammatory Bowel Disease (IBD): Assessment of Inflammatory Bowel Disease Activity and Severity.	N/A	AGA/AMA–PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Steroid Sparing Therapy	N/A	AGA/AMA–PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Steroid Related Iatrogenic Injury—Bone Loss Assessment.	N/A	AGA/AMA–PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization	N/A	AGA/AMA–PCPI
TBD	Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization	N/A	AGA/AMA–PCPI
TBD	Inflammatory Bowel Disease (IBD): Screening for Latent TB Before Initiating Anti–TNF Therapy.	N/A	AGA/AMA–PCPI
TBD	Inflammatory Bowel Disease (IBD): Hepatitis B Assessment Before Initiating Anti–TNF Therapy.	N/A	AGA/AMA–PCPI
226	Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	AMA–PCPI

* This measures group is reportable thought registry-based reporting only.

TABLE 48—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 SLEEP APNEA MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Assessment of Sleep Symptoms	N/A	AMA/PCPI/AASM
TBD	Severity Assessment at Initial Diagnosis	N/A	AMA/PCPI/AASM
TBD	Positive Airway Pressure Therapy Prescribed	N/A	AMA/PCPI/AASM
TBD	Assessment of Adherence to Positive Airway Pressure Therapy	N/A	AMA/PCPI/AASM

* This measures group is reportable thought registry-based reporting only.

TABLE 49—PROPOSED MEASURES IN THE PROPOSED 2012 EPILEPSY MEASURES GROUP

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Seizure Type(s) and Current Seizure Frequency(ies)	N/A	AAN/AMA–PCPI
TBD	Documentation of Etiology of Epilepsy or Epilepsy Syndrome	N/A	AAN/AMA–PCPI
TBD	Querying and Counseling about Anti-Epileptic Drug (AED) Side-Effects	N/A	AAN/AMA–PCPI
TBD	Counseling about Epilepsy Specific Safety Issues	N/A	AAN/AMA–PCPI
TBD	Counseling for Women of Childbearing Potential with Epilepsy	N/A	AAN/AMA–PCPI

TABLE 50—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 DEMENTIA MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Dementia: Staging of Dementia	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Cognitive Assessment	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Functional Status Assessment	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Neuropsychiatric Symptom Assessment	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Management of Neuropsychiatric Symptoms	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Screening for Depressive Symptoms	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Counseling Regarding Safety Concerns	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Counseling Regarding Risks of Driving	N/A	AAN/AGS/AMDA/APA/AMA–PCPI
TBD	Dementia: Caregiver Education and Support	N/A	AAN/AGS/AMDA/APA/AMA–PCPI

* This measures group is reportable thought registry-based reporting only.

TABLE 51—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 PARKINSON'S MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Annual Parkinson's Disease Diagnosis Review	N/A	AAN
TBD	Psychiatric Disorders or Disturbances Assessment	N/A	AAN
TBD	Cognitive Impairment or Dysfunction Assessment	N/A	AAN
TBD	Querying about Sleep Disturbances	N/A	AAN
TBD	Parkinson's Disease Rehabilitative Therapy Options	N/A	AAN
TBD	Parkinson's Disease Related Safety Issues Counseling	N/A	AAN
TBD	Parkinson's Disease Medical and Surgical Treatment Options Reviewed	N/A	AAN

* This measures group is reportable thought registry-based reporting only.

TABLE 52—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 ELEVATED BLOOD PRESSURE MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Aspirin or Other Anti-Platelet or Anti-Coagulant Therapy	N/A	ABIM
TBD	Complete Lipid Profile	N/A	ABIM
TBD	Urine Protein Test	N/A	ABIM
TBD	Annual Serum Creatinine Test	N/A	ABIM
TBD	Diabetes Documentation or Screen Test	N/A	ABIM
TBD	Counseling for Diet and Physical Activity	N/A	ABIM
TBD	Blood Pressure Control	N/A	ABIM
TBD	LDL Control	N/A	ABIM
TBD	Overall Hypertension Care Satisfaction	N/A	ABIM
TBD	Patient Self-care Support	N/A	ABIM

* This measures group is reportable thought registry-based reporting only.

TABLE 53—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 RADIOLOGY MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Reporting to a Radiation Dose Index Registry	N/A	
TBD	Cumulative Count of Potential High Dose Radiation Imaging Studies: CT Scans and Cardiac Nuclear Medicine Scans	N/A	ABMS/ABR/ACR/PCPI
TBD	Utilization of a Standardized Nomenclature for CT Imaging Description	N/A	ABR
TBD	Appropriateness: Follow-up CT Imaging for Incidental Pulmonary Nodules According to Recommended Guidelines.	N/A	ABR
TBD	Overuse: Abdomen, Pelvis or Combined Abdomen/Pelvis CT Studies	N/A	ABR
TBD	Equipment Evaluation for Pediatric CT Imaging Protocols	N/A	ABR
TBD	Utilization of Pediatric CT Imaging Protocols	N/A	ABR
TBD	Search for Prior Imaging Studies through a Secure, Authorized Media-Free Shared Archive.	N/A	ABR
TBD	Images Available for Patient Follow-up and Comparison Purposes	N/A	ABR
TBD	Exposure Time Reported for Procedures Using Fluoroscopy	N/A	PCPI/ACR/NCQA

* This measures group is reportable thought registry-based reporting only.

TABLE 54—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 CARDIOVASCULAR PREVENTION MEASURES GROUP

Physician quality reporting system	Measure title	NQF measure No.	Measure developer
204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	0068	NCQA
236	Controlling High Blood Pressure	0018	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus	0064	NCQA
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA–PCPI
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100	0075	NCQA
TBD	Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years.	N/A	CMS

TABLE 55—PROPOSED MEASURES INCLUDED IN THE PROPOSED 2012 CATARACTS MEASURES GROUP *

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
TBD	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	N/A	AAO
TBD	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	N/A	AAO
191	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	0565	AMA–PCPI/NCQA
192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures.	0564	AMA–PCPI/NCQA

* This measures group is reportable thought registry-based reporting only.

As with measures group reporting in the 2008, 2009, 2010, and 2011 Physician Quality Reporting System, we propose that each eligible professional electing to report a group of measures for 2012 must report all measures in the group that are applicable to each patient or encounter to which the measures group applies at least up to the minimum number of patients required by the applicable reporting criteria. We proposed that the measures proposed for the 2012 Back Pain Measures Group would continue to be reportable only as part of a measures group and not as individual measures for the 2012 Physician Quality Reporting System. Measures selected for inclusion in all other 2012 Physician Quality Reporting System measures groups would be reportable either as individual measures or as part of a measures group.

We note that the specifications for measures groups do not necessarily contain all the specification elements of each individual measure making up the measures group. This is based on the need for a common set of denominator specifications for all the measures making up a measures group in order to define the applicability of the measures group. Therefore, the specifications and instructions for measures groups would be provided separately from the specifications and instructions for the individual 2012 Physician Quality Reporting System measures. We will post the detailed specifications and specific instructions for reporting measures groups on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/PQRS* by no later than December 31, 2011.

Additionally, the detailed measure specifications and instructions for submitting data on those 2012 measures groups that were also included as 2011 Physician Quality Reporting System measures groups may be updated or modified by the measure developer prior to 2012. Therefore, the 2012 Physician Quality Reporting System measure specifications for any given measures group could be different from specifications and submission instructions for the same measures group used for 2011. For example, the measure developer may change the codes contained in the measure's denominator. These measure specification changes do not materially impact the intended meaning of the measures or the strength of the measures. We invite public comment on our proposed retention of all 2011 Physician Quality Reporting System measures groups, as well as our newly proposed measures groups for the 2012 Physician Quality Reporting System.

(5) Proposed 2012 Physician Quality Reporting System Quality Measures for Group Practices Selected To Participate in the GPRO (GPRO)

For 2012, we propose that group practices selected to participate in the 2012 Physician Quality Reporting System GPRO would be required to report on 40 proposed measures listed in Table 55. Specifically, for the 2012 Physician Quality Reporting System, we propose to retain most of the measures available for reporting under the 2011 Physician Quality Reporting System GPRO because of our continued interest in the reporting of those measures as well as to maintain program consistency from year to year. However, for 2012, we propose to retire the following measures that were required under the 2010 and 2011 GPRO (that is, GPRO I for 2011):

- Diabetes Mellitus: Hemoglobin A1c Testing.
- Diabetes Mellitus: Lipid Profile.
- Hypertension (HTN): Blood Pressure Measurement.

Furthermore, we propose to add the following Physician Quality core measures that were not available for reporting via the GPRO for the 2011 Physician Quality Reporting System:

- Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.
- Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention.
- Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100.
- Proportion of adults 18 years and older who have had their blood pressure measured within the preceding 2 years.

In addition to adding the Physician Quality Reporting System core measures that were not available for reporting under the GPRO for the 2011 Physician Quality Reporting System, we propose to add the following measures for reporting under the 2012 Physician Quality Reporting System GPRO:

- Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.
- Adult Weight Screening and Follow-up.
- Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
- Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.
- 30 Day Post Discharge Physician Visit.
- Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.
- Diabetes: Aspirin Use.
- Falls: Screening for Fall Risk.
- Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.
- Diabetes Mellitus: Tobacco Non Use.
- Coronary Artery Disease (CAD): LDL-level < 100 mg/dl.
- Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus (less than 8 percent).
- Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received.
- Monthly International Normalized Ratio (INR) for Beneficiaries on Warfarin.

We propose these new measures because they are NQF-endorsed measures that are consistent with other CMS quality reporting initiatives. We believe it is in the stakeholders' interest to align measures in different initiatives. As stated previously in section (e)(6) of this proposed rule, we propose that

group practices selected to participate in the Physician Quality Reporting System GPRO would be required to report on all measures listed in Table 56.

TABLE 56—PROPOSED MEASURES FOR PHYSICIAN GROUPS PARTICIPATING IN THE 2012 PHYSICIAN QUALITY REPORTING SYSTEM GROUP PRACTICE REPORTING OPTION (GPRO)

Physician quality reporting system No.	Measure title	NQF measure No.	Measure developer
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus (> 9%)	0059	NCQA
2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus	0064	NCQA
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus	0061	NCQA
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0081	AMA–PCPI
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.	0067	AMA–PCPI
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).	0070	AMA–PCPI
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0083	AMA–PCPI
110	Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old	0041	AMA–PCPI
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.	0043	NCQA
112	Preventive Care and Screening: Screening Mammography	0031	NCQA
113	Preventive Care and Screening: Colorectal Cancer Screening	0034	NCQA
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient	0055	NCQA
118	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).	0066	AMA–PCPI
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.	0062	NCQA
163	Diabetes Mellitus: Foot Exam	0056	NCQA
228	Heart Failure: Left Ventricular Function (LVF) Testing		CMS
198	Heart Failure: Left Ventricular Function (LVF) Assessment	0079	AMA–PCPI
227	Heart Failure: Weight Measurement	0085	AMA–PCPI
199	Heart Failure: Patient Education	0082	AMA–PCPI
236	Hypertension (HTN): Blood Pressure Control	0018	NCQA
235	Hypertension (HTN): Plan of Care	0017	AMA–PCPI
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control	0073	NCQA
51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation	0091	AMA–PCPI
226	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	0028	AMA–PCPI
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy	0102	AMA–PCPI
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic	0068	NCQA
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100	0075	NCQA
TBD	Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years.	N/A	CMS
TBD	30-Day Post Discharge Physician Visit	N/A	CFMC
46	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility	0097	AMA–PCPI/NCQA
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA–PCPI
200	Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation	0084	AMA–PCPI
TBD	Diabetes: Aspirin Use	0076	MN Community Measurement
TBD	Falls: Screening for Fall Risk	0101	NCQA
40	Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.	0045	AMA–PCPI/NCQA
128	Adult Weigh Screening and Follow-up	421	CMS/QIP
TBD	Diabetes Mellitus: Tobacco Non-Use	0729	MN Community Management
TBD	Coronary Artery Disease (CAD): LDL-level < 100 mg/dl	N/A	CMS
TBD	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus (< 8%)	575	NCQA
TBD	Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received.	N/A	CMS
TBD	Monthly INR for Beneficiaries on Warfarin	555	CMS

We intend to provide a separate measures specifications document and other supporting documents for group practices participating in the 2012 Physician Quality Reporting System GPRO. We anticipate that the group practice measures specifications document will be available by November 15, 2011 or shortly thereafter on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/PQRS.* We invite public comment on the proposed 2012 Physician Quality Reporting System measures for group practices selected to participate in the 2012 Physician Quality Reporting System GPRO.

g. Maintenance of Certification Program Incentive

Section 3002(c) of the Affordable Care Act amends section 1848(k)(4) of the Act, as amended by section 3002(c) of

the Affordable Care Act, requires the Secretary to address a mechanism whereby an eligible professional may provide data on quality measures through a maintenance of certification program (Maintenance of Certification Program) operated by a specialty body of the American Board of Medical Specialties (ABMS). In addition, section 1848(m)(7) of the Act (''Additional Incentive Payment''), as added by section 10327(a) of the Affordable Care Act, provides for an additional 0.5 percent incentive payment for years 2011 through 2014 if certain requirements are met. In accordance with section 1848(m)(7)(B) of the Act governing the ''Additional Incentive Payment,'' in order to qualify for the additional incentive payment, an eligible professional must—

• Satisfactorily submit data on quality measures under the Physician Quality Reporting System for a year and have such data submitted—

++ On their behalf through a Maintenance of Certification Program that meets the criteria for a registry under the Physician Quality Reporting System; or

++ In an alternative form and manner determined appropriate by the Secretary; and

++ More frequently than is required to qualify for or maintain board certification status:

++ Participate in such a Maintenance of Certification Program for a year; and

++ Successfully complete a qualified Maintenance of Certification Program practice assessment for such year.

Section 1848(m)(7)(C)(i) of the Act defines ''Maintenance of Certification Program'' as a continuous assessment program, such as a qualified ABMS Maintenance of Certification Program, or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communications skills and professionalism. Such a program shall require a physician to do the following:

• Maintain a valid, unrestricted medical license in the United States.

• Participate in educational and self-assessment programs that require an assessment of what was learned.

• Demonstrate, through a formalized, secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

• Successful completion of a qualified Maintenance of Certification Program practice assessment.

As defined in section 1848(m)(7)(C)(ii) of the Act, a ''qualified Maintenance of Certification Program practice assessment'' means an assessment of a physician's practice that—

• Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine;

• Includes a survey of patient experience with care; and

• Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment and then to remeasure to assess performance after such intervention.

To qualify for the additional incentive payment, section 1848(m)(7)(B)(iii) of the Act also requires the Maintenance of Certification Program to submit to CMS, on behalf of the eligible professional, information:

• In a form and manner specified by the Secretary, that the eligible professional more frequently than is required to qualify for or maintain board certification status, participates in the Maintenance of Certification Program for a year and successfully completes a qualified Maintenance of Certification Program practice assessment for such year;

• Upon request by the Secretary, information on the survey of patient experience with care; and

• 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.

In order to qualify for the additional 0.5 percent incentive payment in 2011, eligible professionals were required to participate more frequently in each of the following four parts of the Maintenance of Certification Program:

• Maintain a valid unrestricted license in the United States. For 2011, physicians simply needed to maintain a valid unrestricted license in the United States to meet the requirement for ''more frequent'' participation with respect to this part (75 FR 73541 through 73546).

• Participate in educational and self-assessment programs that require an assessment of what was learned.

• Demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

• Successfully complete a qualified maintenance of certification program practice assessment.

We have received requests from the American Board of Medical Specialties, as well as various specialty organizations, to revise the criteria for satisfying the Maintenance of Certification Program additional incentive, because these entities believe that more frequent participation in all four parts of the Maintenance of Certification Program is too narrow. We have further considered the language under section 1848(m)(7)(B)(ii)(I) of the Act and we believe it can be interpreted more broadly. In particular, we note that the requirement that a professional ''more frequently than is required to qualify for or maintain board certification status participates in such a Maintenance of Certification Program'' could refer to the program as a whole, such that any element performed more frequently than is required satisfies the general requirement. The nature of the various components of a maintenance of certification program also suggest that it is not necessary that each of the four elements of the program be performed more frequently. We previously stated we believe that the ''more frequently'' requirement does not apply to the first part, which states that a physician maintain a valid unrestricted license, as there is no way a physician may maintain a valid unrestricted license ''more frequently.'' As such, we believe that the more frequently requirement could be satisfied based on any of the other elements of the program (that is, educational and self-assessment program; secure examination; or practice assessment). Specifically, we believe that if a professional more frequently than is required satisfies one or more of those parts of a program, the more frequently requirement would be met. Accordingly, we propose that in order to earn an additional 0.5 percent incentive for 2012 through 2014, an eligible professional must participate more frequently than is required in at least one of the following four parts of the Maintenance of Certification Program, as well as ''more frequent'' participation in the practice assessment component. With respect to how to assess whether a professional completes one of the elements of a program ''more frequently,'' we believe that this would be tied to the specific requirements of Board certification for the professional. Given that different specialties have different certification requirements (physician examination requirements to maintain Board certification varies widely depending on specialty), we do

not believe it is appropriate to impose a uniform requirement for all professionals and therefore, we believe that the board could determine for a particular program element the more frequent requirement for the professional. However, we believe that a minimum threshold would need to be met such that the professional would have to do something more frequently or more than what is ordinarily required for a particular part of the program, as well as ''more frequent'' participation in the practice assessment component.

Accordingly, we propose for 2012, 2013, and 2014 the following for each year:

- An eligible professional wishing to be eligible for the additional Physician Quality Reporting System incentive payment of 0.5 percent would be required to meet the proposed requirements for satisfactory Physician Quality Reporting System reporting, for the applicable program year (that is, to qualify for the additional 0.5 percent incentive payment for 2012, meet the 2012 requirements for satisfactory reporting), based on the 12-month reporting period (January 1 through December 31 of the respective program year).
- For purposes of satisfactory reporting under the Physician Quality Reporting System, we propose that the eligible professional may participate as an individual eligible professional using either individual Physician Quality Reporting System measures or measures groups and submitting the Physician Quality Reporting System data via claims, a registry, or an EHR or participate under the GPRO option. As an alternative to this reporting option, we propose that eligible professionals may satisfactorily report under the Physician Quality Reporting System based on submission of Physician Quality Reporting System data by a Maintenance of Certification Program, provided that the Maintenance of Certification Program has qualified as a Physician Quality Reporting System registry for 2012. As indicated previously, an eligible professional would not necessarily have to qualify for the Physician Quality Reporting System through a Maintenance of Certification Program serving as a registry. Rather, we propose that an eligible professional may qualify for the additional incentive, without regard to the method by which the eligible professional has met the basic requirement of satisfactory reporting under the Physician Quality Reporting System.
- In addition to meeting the proposed requirements for satisfactory reporting for the Physician Quality Reporting System for a program year, the eligible professional must have data with respect to the eligible professional's participation in a Maintenance of Certification Program submitted on his or her behalf by a qualified medical specialty board or other entity sponsoring a Maintenance of Certification Program. For each eligible professional that wishes to qualify for the Maintenance of Certification Program Incentive, the qualified medical specialty board or other entity sponsoring a Maintenance of Certification Program must submit data to CMS with respect to the following:
- An eligible professional must, more frequently than is required to qualify for or maintain board certification, participate in a Maintenance of Certification Program for a year and successfully complete a qualified Maintenance of Certification Program practice assessment for such year. With regard to the ''more frequently'' requirement as it applies to the elements of a Maintenance of Certification Program itself (other than completing a qualified Maintenance of Certification Program practice assessment), we propose to require that the Maintenance of Certification Program certify that the eligible professional has ''more frequently'' than is required to qualify for or maintain board certification ''participated in a Maintenance of Certification Program for a year.'' We do not propose to specify with respect to participation how a physician must meet the more frequently requirement, but rather that the Maintenance of Certification Program determine what a physician must do to more frequently participate in a Maintenance of Certification Program and so certify that the eligible professional has met this requirement. While we do not believe that the ''more frequently'' requirement is applicable to the licensure requirement, given that one cannot be licensed ''more frequently'' than is required, we propose to leave it up to the Maintenance of Certification Program to determine which element(s) of a Maintenance of Certification Program must be completed more frequently. We believe that making this change will reduce burden on physicians and will increase participation while being consistent with the requirement to ''more frequently'' participate in a Maintenance of Certification Program.
- With respect to the Maintenance of Certification Program practice assessment, which is specifically delineated in section 1848(m)(7)(B)(ii) of the Act as being required more often than is necessary to qualify for or maintain board certification, we believe we need to be more specific regarding our interpretation of the phrase ''more frequently.'' Additionally, we are aware that some specialty boards have varying Maintenance of Certification Program requirements for physicians to maintain board certification, based on the date of original certification. Some, we believe, may not be required to participate in a Maintenance of Certification Program at all in order to maintain board certification. Accordingly, we recognize that ''more often'' may vary among physicians certified by the same specialty board. We interpret the statutory provisions as requiring participation in and successful completion of at least one Maintenance of Certification Program practice assessment per year. Therefore, we propose, as a basic requirement, participation in and successful completion in at least one Maintenance of Certification Program practice assessment for each year the physician participates in the Maintenance of Certification Program Incentive, regardless of whether or how often the physician is required to participate in a Maintenance of Certification Program to maintain board certification.

We are also aware that ABMS boards are at various stages in implementing the practice assessment modules, and some may not have such assessment modules in place. However, inasmuch as we interpret the statute to require a Maintenance of Certification Program practice assessment at least once per program year as part of the Maintenance of Certification Program, eligible professionals who do not have available, through their boards or otherwise, a Maintenance of Certification Program practice assessment are not eligible for the 0.5 percent incentive.

We believe that the experience of care survey provides particularly valuable information and proposed that a qualified Maintenance of Certification Program practice assessment must include a survey of patient experience with care. The Secretary may request information on the survey of patient experience with care, under section 1848(m)(7)(B)(iii) of the Act. In view of the importance of this information, and the lack of readily available alternative sources, we propose to require that Maintenance of Certification Programs submit information about the patient experience with care survey(s) used by physicians to fulfill the Maintenance of Certification Program practice assessment. We are not, at this time, requesting the results of the survey for the eligible professionals for whom

information is being submitted by the Maintenance of Certification Program. We may, however, request such information for appropriate validation purposes and may propose to request such data for future years of the Maintenance of Certification Program Incentive.

Some Maintenance of Certification Programs underwent a self-nomination process in 2011 to enable their members to be eligible for this Physician Quality Reporting System Maintenance of Certification Program Incentive for 2011 Physician Quality Reporting System. We propose that a Maintenance of Certification Program that was approved after undergoing the self-nomination process in 2011 must submit a self nomination statement for each year the Maintenance of Certification Program intends to participate in the Physician Quality Reporting System Maintenance of Certification Program. In the self-nomination statement, we propose that the previously approved program must provide us with updates to its program in its self-nomination statement. We propose that this self-nomination statement be submitted to CMS via a web-based tool.

For Maintenance of Certification Programs new for 2012, we propose that Maintenance of Certification Programs wishing to enable their diplomates to be eligible for an additional Physician Quality Reporting System incentive payment for the 2012 Physician Quality Reporting System will need to go through a self-nomination process by January 31, 2012. We proposed the board would need to include all of the following information in their self-nomination statement to us:

- 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 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, 2012.
- Indicate that the program has at least 1 active participant.
- The frequency of a cycle of Maintenance of Certification Program for the specific Maintenance of Certification Program of the sponsoring organization; including what constitutes ''more frequently'' for the Maintenance of Certification Program itself and for 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.
- 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 2011 and to be used for 2012, including the title and descriptions of each measure, the owner of the measure, whether the measure is NQF endorsed, and a link to a Web site containing the detailed specifications of the measures, or an electronic file containing the detailed specifications of the measures.

We propose that sponsoring organizations who desire to participate as a Maintenance of Certification Program would need to be able to provide CMS the following information in a CMS-specified file format by no later than the end of the first quarter of 2012:

- The name, NPI and applicable TIN(s) of the eligible professional who would like to participate in this process.
- Attestation from the board that the information provided to CMS is accurate and complete.
- The board has signed documentation from the eligible professional that the eligible professional wishes to have the information released to us.
- Information from the patient experience of care survey.
- Information certifying that 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 that the physician met the board certification requirements for the Maintenance of Certification Program, and the year the eligible professional participated in a Maintenance of Certification Program ''more frequently'' than is required to maintain or qualify for board certification.
- Information certifying that 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 propose that specialty boards that also desire to send Physician Quality Reporting System information to us on behalf of eligible professionals should be able to meet the proposed requirements for registry data submission and should follow the directions for self-nomination to become a qualified registry. Boards may also participate as registries for Physician Quality Reporting System data provided that they meet the registry requirements. As an alternative to requiring boards to either operate a qualified Physician Quality Reporting System registry or to self-nominate to submit Maintenance of Certification Program data to us on behalf of their members, we propose to continue to allow the various boards to submit the Maintenance of Certification Program data to the ABMS and having ABMS submit the information on behalf of the various boards and their member eligible professionals to CMS.

To the extent an eligible professional participates in multiple Maintenance of Certification Programs and meets the requirements under section 1848(m)(7) of the Act (Additional Incentive Payment) under multiple programs, we note that the eligible professional can qualify for only one additional 0.5 percent incentive per year. We invite public comment on our proposals for the Physician Quality Maintenance of Certification Program Incentive for 2012 through 2014.

h. Feedback Reports

Section 1848(m)(5)(H) of the Act requires the Secretary to provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures. Since the inception of the program in 2007, the Physician Quality Reporting System has provided eligible professionals who have reported Physician Quality Reporting System data on quality measures feedback reports at the TIN/NPI level detailing participation in the Physician Quality Reporting System, including reporting rate and performance rate information. For 2008, we improved the format and content of feedback reports based on stakeholder input. We also developed an alternate report distribution method whereby each eligible professional can directly

request and receive a feedback report. In accordance with Section 1848(m)(5)(H) of the Act, we will continue to provide feedback reports to individuals and group practices that attempt to report on at least one Physician Quality Reporting System quality measure. We propose to provide feedback reports for 2012 and beyond on or about the time of issuance of the incentive payments, consistent with our current practice.

We believe it will be beneficial for eligible professionals to also receive interim feedback reports. In the 2011 MPFS Final Rule with comment period, we stated that we intended to provide interim feedback reports to eligible professionals in 2012 (75 FR 73549). Therefore, we propose to provide interim feedback reports for eligible professionals reporting individual measures and measures groups through the claims-based reporting mechanism for 2012 and beyond. These reports would be a simplified version of annual feedback reports that we currently provide for such eligible professionals and would be based on claims for dates of service occurring on or after January 1 and processed by March 31 of the respective program year (that is, January 1, 2012 and processed by March 31, 2012 for the 2012 program year). We expect that we would be able to make these interim feedback reports available to eligible professionals in the summer of the respective program year (that is summer 2012 for the 2012 program year). We believe interim feedback reports would be particularly valuable to eligible professionals reporting measures groups, because it would let an eligible professional know how many more cases he or she needs to report to satisfy the criteria for satisfactory reporting for claims-based reporting of measures groups. We invite public comment on our proposal to continue to provide annual feedback reports as well as our intention to provide interim feedback reports.

i. Informal Review

Under 42 CFR 414.90(i), eligible professionals or group practices may seek an informal review of the determination that the eligible professional or group practice did not satisfactorily submit data on quality measures under the Physician Quality Reporting System.

To maintain program consistency until we have further experience with the informal review process that we implemented for the 2011 Physician Quality Reporting System, we propose to largely retain the same informal review process that was finalized in the 2011 MPFS final rule with comment period (75 FR 73549 through 73551) for 2012 and beyond. Specifically, we propose to base the informal process on our current inquiry process whereby an eligible professional can contact the Quality Net Help Desk (via phone or e-mail) for general Physician Quality Reporting System and eRx Incentive Program information, information on Physician Quality Reporting System feedback report availability and access, and/or information on Physician Quality Reporting System Portal password issues. For purposes of the informal process required under section 1848(m)(5)(E) of the Act, we propose the following inquiry process:

- An eligible professional electing to utilize the informal process must request an informal review within 90 days of the release of his or her feedback report, irrespective of when an eligible professional actually accesses his/her feedback report.
- An eligible professional may request an informal review through use of a web-based tool, if technically feasible. We believe use of the web-based tool will provide a more efficient way to record informal review requests, as web-based tool will guide the eligible professional through the creation of an informal review requests. For example, the web-based tool will prompt an eligible professional of any necessary information s/he must provide. If not technically feasible, we propose that an eligible professional may request the informal review by notifying the Quality Net Help Desk via e-mail at *qnetsupport@sdps.org*. The e-mail requesting the initiation of the informal review process should summarize the concern(s) of the eligible professional and the reason(s) for requesting an informal review.
- We further propose that CMS will provide the eligible professional with a response to his or her request for an informal review within 90 days of receiving the original request. In 2011, we proposed to provide the eligible professional with a response to his or her request for an informal review within 60 days of receiving the original request. However, we anticipate that the volume of informal review requests will grow as participation in the Physician Quality Reporting System grows, particularly as we move towards the implementation of the 2015 payment adjustment. Furthermore, we believe that the time it takes for CMS to calculate data on Physician Quality Reporting System quality measures will be greater than in 2011, since we are proposing additional individual measures and measures groups. For these reasons, we are proposing to amend 42 CFR 414.90(i)(2) to indicate that CMS will provide a written response within 90 days of the receipt of the original request for an informal review.
- As this process is informal and the statute does not require a formal appeals process, we will not include a hearing or evidence submission process, although the eligible professional may submit information to assist in the review.
- Based on our informal review, we will provide a written response. Where we find that the eligible professional did satisfactorily report, we propose to provide the applicable incentive payment.
- Given that this is an informal review process and given the limitations on review under section 1848(m)(5)(E) of the Act, decisions based on the informal review will be final, and there will be no further review or appeal.

We invite public comment on our proposal for the Physician Quality Reporting System informal review process.

j. Future Payment Adjustments for the Physician Quality Reporting System

Beginning in 2015, a payment adjustment will apply under the Physician Quality Reporting System. Specifically, under section 1848(a)(8) of the Act, as added by section 3002(b) of the Affordable Care Act, with respect to covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily submit 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 professionals 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 is—

- 98.5 percent for 2015; and
- 98.0 percent for 2016 and each subsequent year.

Section 1848(8)(A)(i) of the Act provides that, for purposes of the payment adjustment, the ''quality reporting period'' with the respect to a year, is a period specified by the Secretary. In order to maintain consistency and program continuity, similar to the 12-month reporting period we are proposing for 2012, we are also proposing a 12-month reporting period for the 2015 payment adjustment. Specifically, we propose that the reporting period for purposes of the 2015 payment adjustment to be the 2013 calendar year, that is, January 1, 2013 through December 31, 2013. We believe

that this proposed reporting period will allow a full calendar year for eligible professionals to meet the criteria for satisfactory reporting for purposes of the 2015 payment adjustment (that will be proposed in future rulemaking) while still providing us with enough time to collect and analyze the data submitted by eligible professionals for the 2015 payment adjustment without having to make retroactive payment adjustments in 2015. If we determine that an eligible professional or group practice has not satisfactorily reported data on quality measures for the January 1, 2013 through December 31, 2013 reporting period for purposes of the 2015 payment adjustment, then the eligible professional or group practice would be subject to the 1.5 percent adjustment in their fee schedule amount in 2015. We invite public comment on the proposed reporting period for purposes of the 2015 Physician Quality Reporting System payment adjustment.

We intend to address the remaining requirements for satisfactory reporting for purposes of the 2015 payment adjustment in future rulemaking. We welcome suggestions for what the criteria for satisfactory reporting for purposes of the 2015 payment adjustment we might consider in the future with regard to the proposed reporting period described previously.

2. Incentives and Payment Adjustments for Electronic Prescribing (eRx)—The Electronic Prescribing Incentive Program

a. Program Background and Statutory Authority

Electronic prescribing is the transmission using electronic media, of prescription or prescription-related information between the prescriber, dispenser, pharmacy benefit manager (PBM), or health plan, either directly or through an intermediary, including an electronic prescribing network. To encourage the use of electronic prescribing among eligible professionals, section 132 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1848(m) of the Act to establish the eRx Incentive Program. The eRx Incentive Program provides a combination of incentive payments and payment adjustments through 2014 to eligible professionals who are successful electronic prescribers. No eRx incentive payments or payment adjustments are authorized beyond 2014.

From 2009 through 2013, the Secretary is authorized to provide eligible professionals who are successful electronic prescribers an incentive payment equal to a percentage of the eligible professional's total estimated Medicare Part B PFS allowed charges (based on claims submitted not later than 2 months after the end of the reporting period) for all covered professional services furnished by the eligible professional during the respective reporting period. However, section 1848(m)(2)(D) of the Act, as added by section 4101(f)(2)(B) of Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA), which also authorized the Medicare EHR Incentive Program, specifies that the eRx incentive does not apply to an eligible professional, if, for the EHR reporting period, the eligible professional earns an incentive payment under the Medicare EHR Incentive Program beginning in 2011.

The applicable electronic prescribing percent for incentive payments under the eRx Incentive Program are as follows:

- 2.0 percent for 2009.
- 2.0 percent for 2010.
- 1.0 percent for 2011.
- 1.0 percent for 2012.
- 0.5 percent for 2013.

In addition, for years 2012 through 2014, under section 1848(a)(5)(A) of the Act, a PFS payment adjustment applies to eligible professionals who are not successful electronic prescribers at an increasing rate through 2014. Specifically, if the eligible professional is not a successful electronic prescriber for the respective reporting period for the year, the PFS amount for covered professional services during the year shall be a percentage less than the PFS amount that would otherwise apply. The applicable electronic prescribing percent for payment adjustments under the eRx Incentive Program are as follows:

- 1.0 percent in 2012.
- 1.5 percent in 2013.
- 2.0 percent in 2014.

We believe the purpose of the eRx Incentive Program for 2012 and beyond is to continue to encourage significant expansion of the use of electronic prescribing by authorizing a combination of financial incentives and payment adjustments. We are proposing to modify the incentive and payment adjustment language in 42 CFR 414.92 to provide language more consistent with section 1848(k) of the Act.

We believe that the criteria used to determine who is a successful electronic prescriber for purposes of the eRx incentive are not required to be identical to the criteria used to determine the applicability of the eRx payment adjustment. In general, we believe that an incentive should be broadly available to encourage the widest possible adoption of electronic prescribing, even for low volume prescribers. On the other hand, we believe that a payment adjustment should be applied primarily to assure that those who have a large volume of prescribing do so electronically, without penalizing those for whom the adoption and use of an electronic prescribing system may be impractical given the low volume of prescribing. We also believe that eligible professionals who have met the requirements for receiving an incentive payment under the eRx Incentive Program for a particular year have sufficiently demonstrated their adoption and use of electronic prescribing technology and thus should not be subject to the payment adjustment in a future year.

Individual eligible professionals do not have to participate in the Physician Quality Reporting System in order to participate in the eRx Incentive Program (and vice versa). The provisions of the eRx Incentive Program are codified at 42 CFR 414.92.

In prior years, we have proposed and finalized the details of the eRx Incentive Program for each program year through an annual rulemaking process. Through this annual rulemaking process, we have previously established the criteria for avoiding the 2012 eRx payment adjustment in the 2011 PFS Final Rule with comment period (75 FR 73562 through 73565) as well as issued a proposed rule entitled ''Proposed Changes to the Electronic Prescribing (eRx) Incentive Program'' (76 FR 31547), in which we proposed additional changes to the 2012 payment adjustment, as well as the electronic prescribing quality measure for certain reporting periods in 2011. We also established requirements for the 2013 eRx payment adjustment in the 2011 PFS Final Rule with comment period (75 FR 7356).

In this rule, we are setting forth our comprehensive proposals for the 2012 and 2013 incentive payments, additional requirements for the 2013 payment adjustment, and 2014 payment adjustment. We believe that proposing criteria for the eRx Incentive Program for 2012 and beyond will provide eligible professionals with more time to familiarize themselves with the details of the eRx Incentive Program. We hope this will lead to increased, successful participation in the eRx Incentive Program. Details regarding our proposals for the eRx Incentive Program for 2012 and 2013 incentive payments, additional requirements for the 2013 payment adjustment, and the 2014

payment adjustment, including our rationale for such proposals, are described in the following section.

b. Eligibility

For the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, we propose the following two ways eligible professionals may participate in the eRx Incentive Program: (1) As an individual eligible professional; or (2) as part of a group practice reporting option (GPRO) for the eRx Incentive Program (eRx GPRO). Eligible professionals eligible to participate in the eRx Incentive Program are defined at 42 CFR 414.92(b). For more information on which professionals are eligible to participate in the eRx Incentive Program, we refer readers to the Eligible Professionals page of the eRx Incentive Program section of the CMS Web site at: *http://www.cms.gov/ERxIncentive/05_Eligible%20Professionals.asp#TopOfPage.*

(1) Individual Eligible Professionals

(A) Definition of Eligible Professional

As in the 2011 eRx Incentive Program, we propose that, for individual eligible professionals participating in the eRx Incentive Program for purposes of the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, the determination of whether an eligible professional is a successful electronic prescriber will be made at the individual professional level, based on the National Provider Identifier (NPI) number. Inasmuch as some individuals (identified by NPIs) may be associated with more than one practice or Tax Identification Number (TIN), for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, we propose that the determination of whether an eligible professional is a successful electronic prescriber will continue to be made for each unique TIN/NPI combination. Then, as in previous years, incentive payments would be made to the applicable holder of the TIN. We propose continuing to use the TIN/NPI combination as the unit of analysis to maintain program continuity, as individual eligible professionals are already familiar with this level of analysis and payment. We invite public comment on our proposal to continue analyzing data using the TIN/NPI combination while providing payment to the applicable holder of the TIN.

As in prior program years, we propose that individual eligible professionals who wish to participate in the eRx Incentive Program for purposes of the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments may simply start participating. Individual eligible professionals are not required to register or notify CMS they intend to participate; rather, they may simply begin to report the eRx measure. We invite public comment on the proposed process for individual eligible professionals to participate in the eRx Incentive Program.

(2) Group Practices

As required under section 1848(m)(3)(C) of the Act, we established a process under which eligible professionals in a group practice (as defined by the Secretary) would be treated as meeting the requirements for submitting data on electronic prescribing quality measures for covered professional services for a reporting period (or, for purposes of the payment adjustment under section 1848(a)(5) of the Act, for a reporting period for a year) if, in lieu of reporting the electronic prescribing measure, the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time specified by the Secretary. Specifically, we first established the eRx GPRO in 2010, which was further modified in the 2011 PFS Final Rule (75 FR 73502). The eRx GPRO was further modified in 2011. In addition to determining whether an eligible professional is a successful electronic prescriber for incentive payment and payment adjustment purposes based on separately analyzing whether the individual eligible professionals are successful electronic prescribers, we propose to also make the determination that the group practice, as a whole, is a successful electronic prescriber in accordance with section 1848(m)(3)(C) of the Act for those group practices that wish to participate in the eRx GPRO.

(A) Proposed Definition of ''Group Practice''

Section 1848(m)(3)(C)(i) of the Act authorizes the Secretary to define ''group practice,'' which CMS defined by referencing our regulation at § 414.92(b). For the 2011 eRx Incentive Program, a group practice is—

(1) Defined at § 414.90(b), that is participating in the Physician Quality Reporting System; or

(2)(a) In a Medicare approved demonstration project that is deemed to be participating in the Physician Quality Reporting System group practice reporting option; and

(b) Has indicated its desire to participate in the electronic prescribing group practice option.

However, for purposes of determining whether an eRx GPRO is a successful electronic prescriber for CYs 2012 through 2014, we propose to modify the definition of the ''group practice'' at 42 CFR 414.92(b) to be consistent with modifications being proposed to the definition of ''group practice'' at 42 CFR 414.90(b) for the 2012 Physician Quality Reporting System.

Specifically, we propose to modify the language that references Medicare demonstrations to more broadly recognize other similar Medicare programs that group practices may be participating in so that such practices may be eligible to participate in the eRx Incentive Program. In addition, we are making clear that all group practices must indicate their desire to participate in the eRx group practice option. Also, as we noted above, we are proposing to modify the definition of group practice under the Physician Quality Reporting System definition at 42 CFR 414.90(b) by defining a group practice as a single TIN with at least 25 or more eligible professionals, as identified by their individual NPI, who have reassigned their Medicare billing rights to the TIN. Given that the definition of ''group practice'' at 42 CFR 414.92(b) follows the Physician Quality Reporting System definition, if the proposed changes to 414.90(b) are finalized, it would apply to the definition for group practice under the eRx Incentive Program.

Although this proposal would eliminate group practices comprised of 2 to 24 eligible professionals for the purpose of the eRx Incentive Program, we believe this proposal to change the definition of ''group practice'' would not be a significant burden to these small group practices as they may still participate as individual eligible professionals. For 2010, out of 107 group practices that self-nominated to participate in GPRO II for the Physician Quality Reporting System, 68 of these group practices qualified to participate in the eRx Incentive Program under GPRO II. However, during the opt-out period which ended on May 12, 2011, 6 of these 68 group practices dropped out of GPRO II participation, leaving only 62 group practices to participate in GPRO II for 2010. Due to the low participation of only 62 groups, we believe participation in the eRx Incentive GPRO should be limited to only those group practices with 25 or more eligible professionals. Indeed, we believe participating under GPRO II may be more burdensome for very small group practices than participating as

eligible professionals. For example, with respect to the payment adjustment, additional limitations may apply to eligible professionals as individuals that are not applied to group practices, which presents an additional burden to the group practice.

(B) Proposed Process to Participate in the eRx Incentive Program—eRx GPRO

We propose that if a group practice wishes to participate in the eRx Incentive Program under the eRx GPRO, the group practice must self-nominate to do so. To self-nominate, we propose that the group practice follow the requirements for self-nomination under the Physician Quality Reporting System as well as specifically indicate its intent to participate in the eRx Incentive Program as a group practice. A group practice must self-nominate for each calendar year the group wishes to participate in the eRx GPRO. If a group practice self-nominates to participate in the eRx GPRO for a calendar year, then we propose to consider that the group practice is participating in the eRx GPRO for purposes of both the incentive payment (with respect to any incentive payment reporting period that occurs during the calendar year) and the payment adjustment (with respect to any payment adjustment reporting period that occurs during any calendar year). For example, the 2013 payment adjustment reporting period occurs during calendar year 2012 (January 1, 2012 through June 30, 2012). Therefore, any group practice participating in the eRx GPRO during calendar year 2012 would be considered to be participating in the eRx GPRO for both the 2012 incentive and 2013 payment adjustment. Please note that a group practice that is deemed to be participating in the Physician Quality Reporting System, such as an ACO participating under the Medicare Shared Savings Program, will not be deemed participating as a group practice in the eRx Incentive Program. Therefore, the group practice must self-nominate to participate in the eRx Incentive Program under the eRx GPRO. Instructions for submitting the self-nomination statement are the same as the instructions for submitting a self-nomination statement for the Physician Quality Reporting System. Each year, we expect to notify a group practice of the selection decision with respect to participation in the eRx GPRO during the first quarter of the year. We invite public comment on the requirements for eligible professionals to participate as an eRx GPRO for purposes of the eRx Incentive Program.

c. Proposed Reporting Periods

Section 1848(m)(6)(C)(ii) of the Act also authorizes the Secretary to revise the reporting period if the Secretary determines such revision is appropriate, produces valid results on measures reported, and are consistent with the goals of maximizing scientific validity and reducing administrative burden.

(1) Proposed Reporting Periods for the 2012 and 2013 eRx Incentives

Section 1848(m)(6)(C)(i)(II) of the Act defines ''reporting period'' under the eRx Incentive Program for years after 2008 to be the entire year. We also have authority under section 1848(m)(6)(C)(ii) of the Act to revise the reporting period. We propose, however, entire calendar year reporting periods for the reporting period for purposes of the 2012 and 2013 incentive payment (January 1, 2012 through December 31, 2012 for the 2012 incentive and January 1, 2013 through December 31, 2013 for the 2013 incentive, respectively). Accordingly, we propose to modify 42 CFR 414.92(d)(1).

(2) Proposed Reporting Periods for the 2013 and 2014 eRx Payment Adjustments

As we indicated, using our authority under Section 1848(m)(6)(C)(ii) of the Act, in the 2011 PFS Final Rule with comment period, we finalized two different reporting periods: A 6-month reporting period (between January 1, 2011 and June 30, 2011) for purposes of the 2012 payment adjustment for both individual eligible professionals and group practices participating in the eRx GPRO (75 FR 73562 through 73563) and a 12-month reporting period (between January 1, 2011 and December 31, 2011) for purposes of the 2013 payment adjustment for individual eligible professionals and group practices participating in the eRx GPRO (75 FR 73565).

In addition to the 12-month reporting period finalized in the 2011 PFS Final Rule with comment period, we propose an additional 6-month reporting period for purposes of the 2013 payment adjustment. As stated in the CY 2011 PFS final rule with comment period (75 FR 73565), we indicated that we might consider in future rulemaking additional reporting periods for purposes of the 2013 payment adjustment to maximize the opportunities for eligible professionals to become successful electronic prescribers.

As such, we propose for both individual eligible professionals and group practices participating in the eRx GPRO a 6-month reporting period (between January 1, 2012 and June 30, 2012) for purposes of the 2013 payment adjustment.

For similar reasons, we propose a 12-month reporting period (between January 1, 2012 and December 31, 2012) that would apply to individual eligible professionals and a 6-month reporting period (between January 1, 2013 and June 30, 2013) that would apply to both individual eligible professionals and group practices with regard to the 2014 payment adjustment.. (Please note that we are not proposing the 12-month reporting period for group practices for purposes of the 2014 payment adjustment because it is the same proposed reporting period for the 2013 incentive.) Providing two different reporting periods will provide eligible professionals with two opportunities to become successful electronic prescribers. We invite public comment on the proposed reporting periods for the 2013 and 2014 payment adjustments.

d. Proposed Criterion for Determining Successful Electronic Prescribers

Section 1848(m)(3)(B) of the Act governs the requirements for ''successful electronic prescriber,'' for purposes of the incentive payment under section 1848(m)(2) of the Act and the payment adjustment under section 1848(a)(5) of the Act. The Secretary is authorized to use one of two possible criteria for determining whether an eligible professional is a successful electronic prescriber. One criterion, under section 1848(m)(3)(B)(ii) of the Act, is based on the eligible professional's reporting, in at least 50 percent of the reportable cases, on any electronic prescribing measures that have been established under the Physician Quality Reporting System, and are applicable to services furnished by the eligible professional for the reporting period. However, for years after 2009, section 1848(m)(3)(D) of the Act permits the Secretary in consultation with stakeholders and experts to revise the criteria for submitting data on electronic prescribing measures under section 1848(m)(3)(B)(ii) of the Act.

The second criterion, under section 1848(m)(3)(B)(iii) of the Act, is based on the electronic submission by the eligible professional of a sufficient number (as determined by the Secretary) of prescriptions under Part D during the reporting period. If the Secretary decides to use this standard, then, in accordance with section 1848(m)(3)(B)(iv) of the Act, the Secretary is authorized to use Part D

drug claims data to assess whether a sufficient number of prescriptions have been submitted by eligible professionals. However, under section 1848(m)(3)(B)(i) of the Act, if the standard based on a sufficient number (as determined by the Secretary) of electronic Part D prescriptions is applied for a particular reporting period, then the standard specified in law, based on the reporting on electronic prescribing measures would no longer apply.

We considered use of the second criterion for determining successful prescribing under the eRx Incentive Program. While we recognize the benefits of using Part D data as the standard for determining successful electronic prescribers, we believe use of Part D prescriptions for analysis may be premature. For example, as the use of Part D data is fairly new, there is uncertainty as to the accuracies of reporting electronic prescribing activities. For example, if an electronic prescription is converted to a facsimile when reaching the pharmacy, under reporting of Part D data, the transmission is still reported as a pure, electronic prescribing event. Furthermore, use of Part D data would require a complete overhaul of the current requirements for the eRx Incentive Program. For instance, if we choose to shift to the use of Part D data, the program would have to adopt a new form of measurement, a new form of analysis other than use of an eligible professionals' TIN/NPI (as no TIN is populated under Part D data), and new criteria for eligible professionals and eRx GPROs to become successful electronic prescribers. Therefore, we are not proposing to use the second criterion.

For the reasons stated previously, we propose to continue to require eligible professionals to report on the electronic prescribing measure used in 2011 to determine whether an eligible professional is a successful electronic prescriber for the remainder of the eRx Incentive Program. Please note, however, we also are proposing in section IV.F.2.(d).(1). of this proposed rule to modify the electronic quality measure's specifications and to use modified reporting criteria based on the authority provided under section 1848(m)(3)(D) of the Act. We invite public comment on the continued use of reporting the electronic prescribing quality measure for purposes of the ''successful electronic prescriber'' determination under the program.

(1) Reporting the Electronic Prescribing Quality Measure

The proposed electronic prescribing quality measure, similar to the Physician Quality Reporting System measures, has two basic elements, which include: (1) A reporting denominator that defines the patient population on which the eligible professional's performance is being measured; and (2) a reporting numerator, which identifies whether or not a clinical quality action was performed. Our proposals specified later in this section apply to the following eRx Incentive Program years: The 2012 eRx incentive payment; the 2013 eRx incentive payment; the 2013 eRx payment adjustment; and the 2014 eRx payment adjustment.

Under section 1848(k)(2)(C)(i) of the Act, the electronic prescribing measure, which was initially introduced under the Physician Quality Reporting System, shall be a measure selected by the Secretary that has been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. Currently, that entity is the National Quality Forum (NQF). The electronic prescribing measure we propose to retain, NQF Measure #0486: Adoption of Medication e-Prescribing, is currently endorsed by the NQF.

(2) The Denominator for the Electronic Prescribing Measure

The denominator for the electronic prescribing quality measure consists of specific billing codes for covered professional services.

As initially required under section 1848(k)(2)(A)(ii) of the Act, and further established through rulemaking and under section 1848(m)(2)(B) of the Act, we may modify the codes making up the denominator of the electronic prescribing measure. As such, we expanded the scope of the denominator codes for 2010 to covered professional services outside the professional office and outpatient setting, such as professional services furnished in skilled nursing facilities or the home care setting. For 2011, we finalized the following CPT and HCPCS codes in the denominator of the electronic prescribing measure: 90801, 90802, 90804, 90805, 90806, 90807, 90808, 90809, 90862, 92002, 92004, 92012, 92014, 96150, 96151, 96152, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0101, G0108, and G0109 (75 FR 73555). For purposes of reporting periods during CYs 2012 and 2013, we propose to retain these CPT and HCPCS codes in the denominator of the electronic prescribing measure because we believe that these codes represent the types of services for which prescriptions are likely to be generated. Therefore, if we were to measure an eligible professional's performance on the electronic prescribing measure, we would want to do so only for patients who saw the professional for such services. For purposes of the 2012 and 2013 incentives and 2013 and 2014 payment adjustment, we propose to retain the denominator codes contained in the 2011 electronic prescribing measure. Whereas in prior years we only permitted eligible professionals to report the electronic prescribing measure's numerator in connection with a service in the measure's denominator, as discussed in section IV.F.2.i. of this proposed rule, we are proposing to depart from this requirement for purposes of the 2013 and 2014 payment adjustments.

(3) The Reporting Numerator for the Electronic Prescribing Measure

Currently, the electronic prescribing measure's numerator consists of a single code, G8553, which indicates that at least 1 prescription created during the encounter was generated and transmitted electronically using a qualified electronic prescribing system.

For purposes of reporting the measure for the 2012 and 2013 incentives or the 2013 and 2014 payment adjustment, as in prior years, we propose that an eligible professional or group practice participating in the eRx GPRO can report the code associated with the measure's numerator whenever a prescription is generated and transmitted electronically.

We propose to post the final electronic prescribing measure specifications on the ''eRx Measure'' page of the eRx Incentive Program section of the CMS Web site at *http://www.cms.gov/ERXIncentive* by no later than—

- December 31, 2011 for the reporting periods that occur during calendar year 2012.
- December 31, 2012 for the reporting periods that occur during calendar year 2013.

In the event that additional changes are needed to the measure specifications for years after 2012, we would do so via notice and comment rulemaking prior to posting the final measure specifications for that year. We invite public comment on the proposed numerator for the

electronic prescribing measure for CYs 2012 through 2013.

e. Required Functionalities and Part D Electronic Prescribing Standards

As previously stated, to report the electronic prescribing measure, we propose that the eligible professional or group practice must report the measure's numerator G-code. When reporting this G-code for incentive payment or payment adjustment purposes, we propose, for purposes of the 2012 and 2013 incentive and 2013 and 2014 payment adjustment that the eligible professional or eRx GPRO must have and regularly use a ''qualified'' electronic prescribing system, which we further propose to define as either a system with functionalities identified in the electronic prescribing measure specifications, or Certified EHR Technology as defined at 42 CFR 495.4 and 45 CFR 170.102. This proposal is consistent with our June 1, 2011 proposed rule for the 2011 eRx Incentive Program (76 FR 31549).

We are aware that there are significant numbers of eligible professionals who are interested in participating in the eRx Incentive Program but currently do not have an electronic prescribing system or Certified EHR Technology. The electronic prescribing measure does not require the use of any particular system or transmission network; only that the system be a ''qualified'' system.

If the professional does not have general access to an electronic prescribing system or Certified EHR Technology in the practice setting, the eligible professional would not be able to report the electronic prescribing measure. In addition to not being eligible for an incentive payment, an eligible professional who does not report the electronic prescribing measure for 2012 or 2013 would be subject to the 2013 or 2014 eRx payment adjustment, unless an exception applied. We invite public comment on the proposed technological requirements of the electronic prescribing quality measure.

(1) ''Qualified'' Electronic Prescribing System

We propose to retain what constitutes a ''qualified'' electronic prescribing system as a system based upon certain required functionalities that the system can perform. We propose to retain the same functionalities that were required in 2010 and 2011. Therefore, for 2012 through 2014, we propose that a ''qualified'' electronic prescribing system is one that can do the following:

- Generate a complete active medication list incorporating electronic data received from applicable pharmacies and PBMs, if available.
- Enable eligible professionals to select medications, print prescriptions, electronically transmit prescriptions, as well as provide notifications (that is, signals to warn the prescriber of possible undesirable or unsafe situations including potentially inappropriate dose or route of administration of a drug, drug-drug interactions, allergy concerns, or warnings and cautions). This functionality must be enabled.
- Provide information related to lower cost, therapeutically appropriate alternatives (if any). The ability of an electronic prescribing system to receive tiered formulary information, if available, would again suffice for this requirement for reporting the electronic prescribing measure during the reporting periods occurring in CYs 2012 and 2013 until this function is more widely available in the marketplace.
- Provide information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan (if available).

We invite public comment on the proposed definition of a ''qualified electronic prescribing system,'' for systems that have these four functionalities.

Furthermore, we are proposing to expand the definition of a ''qualified electronic prescribing system'' in the electronic prescribing measure that would be used for reporting periods that occur during CY 2012 and 2013 to include Certified EHR Technology as defined at 42 CFR 495.4 and 45 CFR 170.102 because we believe the technological requirements for eRx in the EHR Incentive Program are similar to the technological requirements for the eRx Incentive Program. We also desire to align the requirements of the eRx and the Medicare EHR Incentive Program in order to potentially reduce unnecessary investment in multiple technologies for purposes of meeting the requirements for each program. This proposal is consistent with our June 1, 2011 proposed rule for the 2011 eRx incentive and the 2013 eRx payment adjustment (76 FR 31549).

(2) Part D Electronic Prescribing Standards

Section 1848(m)(3)(B)(v) of the Act specifies that to the extent practicable, in determining whether an eligible professional is a successful electronic prescriber, ''the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program under section 1860D–4(e) of the Act''. The Part D standards for electronic prescribing systems establish which electronic standards Part D sponsors, providers, and dispensers must use when they electronically transmit prescriptions and certain prescription related information for Part D covered drugs that are prescribed for Part D eligible individuals.

To be a qualified electronic prescribing system under the eRx Incentive Program, electronic systems must convey the information listed previously using the standards currently in effect for the Part D electronic prescribing program. Additional Part D electronic prescribing standards were implemented April 1, 2009. On July 1, 2010, we published an Interim Final Rule providing additional updates to Part D electronic prescribing standards. These latest Part D electronic prescribing standards, and those that had previously been adopted, can be found on the CMS Web site at *http://www.cms.gov/eprescribing.*

To ensure that eligible professionals utilize electronic prescribing systems that meet these requirements, the electronic prescribing measure requires that those functionalities required for a ''qualified'' electronic prescribing system utilize the adopted Part D electronic prescribing standards. We propose to modify the Part D electronic prescribing standards required for a ''qualified'' electronic prescribing system under the eRx Incentive Program to have these standards consistent with current, CMS Part D electronic prescribing standards. The Part D electronic prescribing standards relevant to the four functionalities described previously are as follows:

- Generate medication list—Use the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8 or 10.6, Release 1, October 2005 (hereinafter ''NCPDP SCRIPT 8.1 or 10.6'') Medication History Standard. Use of NCPDP SCRIPT 10.6 is a new option for use in the eRx Incentive Program.
- Transmit prescriptions electronically—Use the NCPDP SCRIPT 8.1or 10.6 for the transactions listed at § 423.160(b)(2).
- Provide information on lower cost alternatives—Use the NCPDP Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (hereinafter ''NCPDP Formulary and Benefits 1.0'').

• Provide information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan use:

++ NCPDP Formulary and Benefits 1.0 for communicating formulary and benefits information between prescribers and plans.

++ Accredited Standards Committee (ASC) X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1, October 2002, Washington Publishing Company, 004010X092A1 for communicating eligibility information between the plan and prescribers.

++ NCPDP Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 for communicating eligibility information between the plan and dispensers.

However, there are Part D electronic prescribing standards that are in effect for functionalities that are not commonly utilized at this time. One example is Rx Fill Notification, which is discussed in the Part D electronic prescribing final rule (73 FR 18926). For purposes of the eRx Incentive Program for CYs 2012 through 2014, we again are not requiring that an electronic prescribing system contain all functionalities for which there are available Part D electronic prescribing standards since many of these functionalities are not commonly available. For those required functionalities previously described, we propose that a ''qualified'' system must use the adopted Part D electronic prescribing standards listed previously for electronic messaging only.

There are other aspects of the functionalities for a ''qualified'' system that are not dependent on electronic messaging and are part of the software of the electronic prescribing system, for which Part D standards for electronic prescribing do not pertain and are not required for purposes of the eRx Incentive Program. For example, the requirements in the second functionality that require the system to allow professionals to select medications, print prescriptions, and conduct alerts are functions included in the particular software, for which Part D standards for electronic messaging do not apply.

As stated previously, we are proposing to expand the definition of what constitutes a ''qualified'' electronic prescribing system under the electronic prescribing system to also recognize as ''qualified'' Certified EHR Technology. Among other requirements, Certified EHR Technology must be able to electronically generate and transmit prescriptions and prescription-related information in accordance with certain standards, some of which have been adopted for purposes of electronic prescribing under Part D. Similar to the four functionalities previously noted with regard to a qualified eRx system, Certified EHR Technology also must be able to check for drug-drug interactions and check whether drugs are in a formulary or a preferred drug list, although the certification criteria do not specify any standards for the performance of those functions. We believe that it is acceptable that not all of the Part D eRx standards are required for Certified EHR Technology in light of our desire to better align the requirements of the eRx and the Medicare EHR Incentive Program and potentially reduce unnecessary investment in multiple technologies for purposes of meeting the requirements for each program. Furthermore, to the extent that an eligible professional uses Certified EHR Technology to electronically prescribe under Part D, he or she would still be required to comply with the Part D standards to do so.

f. Proposed Reporting Mechanisms for the 2012 and 2013 Reporting Periods

For purposes of the 2011 incentive payment and 2013 payment adjustment, an eligible professional (and eRx GPRO, for purposes of the 2011 incentive) may report on the electronic prescribing measure to meet the criteria for being a successful electronic prescriber via three reporting mechanisms—claims, qualified registry, and qualified EHR product. However, for purposes of the 2012 payment adjustment, due to operational limitations, only the claims-based reporting mechanism is available for purposes of reporting on the electronic prescribing measure for the 2012 payment adjustment (75 FR 73563).

For reporting periods that occur during CY 2012 and 2013, to provide eligible professionals and groups practices with multiple mechanisms to report on the electronic prescribing measure for purposes of reporting the electronic prescribing measure for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, we propose the following three reporting mechanisms—claims, qualified registry, and qualified EHR. However, as in the past, we would not combine data on the electronic prescribing measure submitted via multiple reporting mechanisms. Combining data received via multiple reporting mechanisms would add significant complexity to our analytics and potentially delay incentive payments. Therefore, we are proposing that an eligible professional or eRx GPRO would need to meet the relevant reporting criteria for the incentive or payment adjustment using a single reporting mechanism.

For reporting periods that occur during CYs 2012 and 2013, we also propose that a group practice that wishes to participate in the eRx Incentive Program as an eRx GPRO for a particular calendar year will have to indicate which reporting mechanism the group practice intends to use to report the electronic prescribing measure. That is, the group practice will need to indicate at the time it self-nominates which reporting mechanism (claims, qualified registry, or qualified EHR) the group practice intends to use for purposes of participating in the eRx GPRO.

The proposed requirements for each reporting mechanism with respect to the 2012 and 2013 incentives and 2013 and 2014 payment adjustments are described below.

(1) Claims-Based Reporting

First, for purposes of reporting the electronic measure for the 2012 and 2013 incentives as well as the 2013 and 2014 payment adjustments, we propose to again retain the claims-based reporting mechanism that has been used since the implementation of the eRx Incentive Program in 2009 for all remaining incentive and payment adjustment years. We are not proposing any prerequisites, such as registration, to begin reporting on the electronic prescribing measure via claims. Retaining the claims-based mechanism allows eligible professionals and group practices to begin to report on the electronic prescribing measure without the added cost of submitting data to a registry or purchasing an EHR system (if the eligible professional is using a standalone eRx system) as eligible professionals already report PFS charges via claims.

If an eligible professional or group practice chooses the claims-based reporting mechanism, we propose that the eligible professional or group practice must directly submit data on the electronic prescribing measure. For eligible professionals and group practices participating in the eRx GPRO using the proposed claims-based reporting mechanism for purposes of

reporting the electronic prescribing measure during a 12-month incentive or payment adjustment reporting period, we propose that all claims for services must be processed by us no later than two months after the respective reporting period, for the claim to be included in our data analysis. (For example, for an eligible professional using the 12-month, 2014 payment adjustment reporting period, all claims for services between January 1, 2012 and December 31, 2012 must be processed no later than February 28, 2013 to be included in our data analysis.) For eligible professionals and group practices using the proposed claims-based reporting mechanism for purposes of reporting the electronic prescribing measure during a 6-month payment adjustment reporting period, we propose that all claims for services must be processed by us by no later than one month after the respective reporting period, for the claim to be included in our data analysis (for example, for an eligible professional using the 6-month, 2013 payment adjustment reporting period, all claims for services between January 1, 2012 and June 30, 2012 must be processed no later than July 31, 2012, for the claims to be included in our data analysis.) We believe that these proposed reporting periods will allow sufficient time for eligible professionals to report the electronic prescribing measure, allow us to collect and analyze the data submitted by eligible professionals, and avoid retroactive adjustments of payments. We invite public comment on our proposal to retain claims-based reporting as a reporting mechanism for the eRx Incentive Program.

(2) Registry-Based Reporting

In addition, for purposes of reporting for the 2012 and 2013 incentives as well as the 2013 and 2014 payment adjustments, to provide an opportunity for individual eligible professionals and group practices who choose to participate in the Physician Quality Reporting System via registry to use the same reporting mechanism for reporting the electronic prescribing measure, we propose to continue the registry-based reporting mechanism introduced under the 2010 eRx Incentive Program. Retaining the registry-based reporting option provides eligible professionals and group practices with another alternative to reporting. In addition, unlike claims-based reporting, although there may be a cost associated with submitting data to a registry, reporting of the electronic prescribing measure to CMS is done entirely by the registry.

We note that there may be a cost associated with submitting data to a registry. As in prior program years, we propose that only registries qualified to submit quality measure results and numerator and denominator data on quality measures on behalf of eligible professionals for the Physician Quality Reporting System for the applicable calendar year would be qualified to submit measure results and numerator and denominator data on the electronic prescribing measure on behalf of eligible professionals for the eRx Incentive Program.

Some registries that self-nominate to become a qualified registry for the Physician Quality Reporting System may not choose to self-nominate to become a qualified registry for purposes for the eRx Incentive Program. Registries need to indicate their desire to qualify to submit measure results and numerator and denominator data on the electronic prescribing measure for reporting periods that occur during CYs 2012 and 2013 at the time that they submit their self-nomination letter for the 2012 and 2013 Physician Quality Reporting System respectively. The self-nomination process and requirements for registries for the Physician Quality Reporting System, which also will apply to the registries for the eRx Incentive Program, are discussed in the Physician Quality Reporting System section IV.F.1.(d).(2). of this proposed rule. We would post a final list of qualified registries for the eRx Incentive Program for CYs 2012 and 2013 on the eRx Incentive Program section of the CMS Web site at *http://www.cms.gov/ERXIncentive* when we post the final list of qualified registries for the Physician Quality Reporting System for 2012 and 2013 respectively on the Physician Quality Reporting System section of the CMS Web site.

Since we are proposing a 12-month reporting period for purposes of the 2012 and 2013 incentive and 6 and 12-month reporting periods for purposes of the 2013 and 2014 payment adjustments (as described in the section previously), we further propose that qualified registries would need to submit the electronic prescribing measure for the eRx Incentive Program to us in two separate transmissions, based on the proposed reporting periods for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments. Specifically, we propose that qualified registries would need to submit 2012 and 2013 data on the electronic prescribing measure in two separate submissions:

- Following the end of the respective 6-month payment adjustment reporting period (between July 1, 2012 and August 19, 2012, for purposes of the 2013 eRx payment adjustment, and between July 1, 2013 and August 19, 2013, for purposes of the 2014 eRx payment adjustment); and
- Following the end of the 12-month reporting period for the 2012 and 2013 incentives and 2014 payment adjustment.

We invite public comment on our proposals regarding registry-based reporting for the 2012, 2013, and 2014 eRx Incentive Program.

(3) EHR-Based Reporting

For purposes of reporting for the 2013 incentive as well as the 2013 and 2014 payment adjustments, in order to provide an opportunity for eligible professionals and group practices who choose to participate in the Physician Quality Reporting System via EHR as well as eligible professionals who participate in the Medicaid or Medicare EHR Incentive Program to use the same reporting mechanism for reporting the electronic prescribing measure, we propose to retain the EHR-Based reporting mechanism to encourage the use of EHR technology as well as provide eligible professionals and group practices with a third reporting option.

Similar to registry-based reporting, we propose that direct EHR technology as well as EHR data submission vendors (as described in our proposals to the Physician Quality Reporting System) ''qualified'' to submit extracted Medicare clinical quality data to us for the Physician Quality Reporting System would be able to be used by an eligible professional or group practice to submit data on the electronic prescribing measure for the 2012 and 2013 incentives and 2013 and 2014 payment adjustments. The self-nomination process and requirements for direct EHR products and EHR data submission vendors for the Physician Quality Reporting System as discussed previously in section IV.F.1.d.(3). of this proposed rule in our 2012 proposals for the Physician Quality Reporting System, would continue to apply to the EHR products and EHR data submission vendors for the eRx Incentive Program. We hope this third reporting option for eligible professionals and group practices will encourage the use of EHR technology.

We propose that direct EHR products and EHR data submission vendors be required to indicate their desire to have one or more of their EHR products approved for the purpose of an eligible professional potentially being able to submit data on the electronic prescribing measure for the eRx

Incentive Program for reporting periods that occur in CYs 2012 and 2013 at the time they self-nominate for the respective 2012 and 2013 Physician Quality Reporting System. A list of approved EHR technology, their vendors (including the technology's version that is approved) for the eRx Incentive Program would be posted on the eRx Incentive Program section of the CMS Web site at *http://www.cms.gov/ERXIncentive* when we post the list of approved EHR technology for the Physician Quality Reporting System on the Physician Quality Reporting System section of the CMS Web site.

Since we are proposing two reporting periods with respect to the 2013 and 2014 payment adjustments (described in section (c)(2) previously), we further propose that eligible professionals using their approved EHR systems would need to submit the electronic prescribing measure for the eRx Incentive Program to us in two separate transmissions, based on the proposed reporting periods for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments. Specifically, we propose that eligible professionals would need to submit 2012 and 2013 data on the electronic prescribing measure in two separate submissions:

- Following the end of the respective 6-month payment adjustment reporting period (between July 1, 2012 and August 19, 2012, for purposes of the 2013 eRx payment adjustment, and between July 1, 2013 and August 19, 2013, for purposes of the 2014 eRx payment adjustment); and
- Following the end of the 12-month reporting period for the 2012 and 2013 incentives and 2014 payment adjustment.

We invite public comment on our proposals with regard to EHR-Based reporting.

g. The 2012 and 2013 eRx Incentives

42 CFR 414.92(d) states the requirements for individual eligible professionals to qualify to receive an incentive payment. We are proposing to modify 42 CFR 414.92(d) to add ''being a,'' so that the provision reads:

In order to be considered a successful electronic prescriber and qualify to earn an electronic prescribing incentive payment (subject to paragraph (c)(3) of this section), an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber under section 1848(m)(3)(B) of the Act and as specified by CMS during the reporting period specified in paragraph (d)(1) of this section and using one of the reporting mechanisms specified in paragraph (d)(2) of this section. Although an eligible professional may attempt to qualify for the electronic prescribing incentive payment using more than one reporting mechanism (as specified in paragraph (d)(2) of this section), the eligible professional will receive only one electronic prescribing incentive payment per TIN/NPI combination for a program year.

We believe this change provides more clarity to the provision.

(1) Applicability of 2012 and 2013 eRx Incentives for Eligible Professionals and eRx GPROs

Section 1848(m)(2)(B) of the Act imposes a limitation on the eRx incentive payment. The Secretary is authorized to choose 1 of 2 possible criteria for determining whether or not the limitation applies to a successful electronic prescriber:

- Whether Medicare Part B allowed charges for covered professional services to which the electronic prescribing quality measure applies are less than 10 percent of the total Medicare Part B PFS allowed charges for all covered professional services furnished by the eligible professional during the reporting period; OR
- The second criterion, under section 1848(m)(3)(B)(iii) of the Act, is based on whether the eligible professional submits (both electronically and non-electronically) a sufficient number (as determined by the Secretary) of prescriptions under Part D (which can, again, be assessed using Part D drug claims data). If the Secretary decides to use this criterion, the criterion based on the reporting on electronic prescribing measures would no longer apply.

Based on our proposal to make the determination of whether an eligible professional or group practice is a ''successful electronic prescriber'' based on submission of the electronic prescribing measure (the first criterion), we propose to apply the criterion under section 1848(m)(2)(B)(i) of the Act for the limitation for both the 2012 and 2013 incentives. Specifically, a successful electronic prescriber is eligible for the 2012 and/or 2013 incentive only if the Medicare Part B allowed charges for covered professional services to which the electronic prescribing quality measure applies comprise at least 10 percent of the total Medicare Part B PFS allowed charges for all covered professional services furnished by the eligible professional or group practice during the reporting period.

For purposes of the 2012 and 2013 incentives, this analysis would be performed during the first quarters of 2013 and 2014 respectively by dividing the eligible professional's or group practice's (for those group practices participation in the eRx GPRO for that year) total 2012 and 2013 respective Medicare Part B PFS allowed charges for all such covered professional services submitted for the measure's denominator codes by the eligible professional's or group practices' total Medicare Part B PFS allowed charges for all covered professional services. If the result is 10 percent or more, then the statutory limitation would not apply and a successful electronic prescriber would qualify to earn the electronic prescribing incentive payment. If the result is less than 10 percent, then the statutory limitation would apply and the eligible professional or group practice would not earn an electronic prescribing incentive payment even if he or she meets the reporting criteria for being a successful electronic prescriber. Although an individual eligible professional or group practice may decide to conduct his or her own assessment of how likely this statutory limitation is expected to apply to him or her before deciding whether or not to report the electronic prescribing measure, an individual eligible professional or group practice may report the electronic prescribing measure without regard to the statutory limitation for the incentive payment. We invite public comment on our proposed use of the 10 percent limitation with respect to the 2012 and 2013 incentive payments.

(2) Proposed Reporting Criteria for Being a Successful Electronic for the 2012 and 2013 eRx Incentives—Individual Eligible Professionals

As discussed previously, section 1848(m)(3)(D) of the Act authorizes the Secretary to revise the criteria for submitting data on the electronic prescribing measure under section 1848(m)(3)(B)(ii) of the Act, which requires the measure to be reported in at least 50 percent of the cases in which the measure is reportable. For 2010 and 2011, we revised that criterion, such that an eligible professional is a successful electronic prescriber by reporting the electronic prescribing quality measure for a minimum of 25 unique visits per year of applicable cases in the denominator.

For the 2012 and 2013 incentives, to maintain program consistency form year to year, we propose to make the determination of whether an eligible professional is a successful electronic prescriber for purposes of the incentive based on a count of the number of times (minimum threshold of 25) an eligible professional reports that at least one prescription created during the denominator-eligible encounter is generated using a qualified electronic

prescribing system, which would include Certified EHR Technology (that is, reports the G8553 code when the eligible professional bills for one of the services included in the measure's denominator). We believe this criterion adequately addresses the goal of the eRx Incentive Program, specifically to promote the use of electronic prescribing systems. We invite public comment on the proposed criteria for successful electronic prescriber with regard to reporting the electronic prescribing quality measure by individual eligible professionals for purposes of qualifying for the 2012 and 2013 eRx incentive payments.

(3) Proposed Criteria for Being a Successful Electronic Prescriber 2012 and 2013 eRx Incentives—Group Practices

Under section 1848(m)(3)(B) of the Act, in order to qualify for the incentive payment, an eligible professional or group practice must be a ''successful electronic prescriber.''

For a group practice to be a successful electronic prescriber for purposes of the 2011 incentive payment, depending on the group's size, a group practice was required to report the electronic prescribing measure for a minimum of 75 to 2,500 unique visits per year of applicable cases in the electronic prescribing measure's denominator. Specifically, 2011 eRx GPRO comprised of 26 to 50 eligible professionals are required to report the electronic prescribing measure for at least 475 unique visits. 2011 group practices comprised of 51 to 100 eligible professionals are required to report the electronic prescribing measure for at least 925 unique visits, and 2011 group practices comprised of 101 to 199 eligible professionals are required to report the electronic prescribing measure for at least 1,875 unique visits.

Because we seek to simplify the reporting criteria for group practices using the eRx GPRO, we propose that, for the 2012 and 2013 incentive payments and 2013 and 2014 payment adjustments, for a group practice using the eRx GPRO to be a successful prescriber, a group practice using the eRx GPRO must report the electronic prescribing measure's numerator for at least 625 unique visits (for group practices comprised of 25–99 eligible professionals) or 2,500 unique visits (for group practices comprised of 100 or more eligible professionals). To obtain these reporting criteria, we multiplied the smallest group practice size for each respective threshold (that is, 25 for the first threshold and 100 for the second threshold) by the number of unique visits (25) an individual eligible professional must report on the electronic prescribing measure in order to qualify for an incentive payment. Although this may be a higher reporting threshold for group practices using the eRx GPRO comprised of 25–50 eligible professionals and group practices using the eRx GPRO comprised of 101–199 eligible professionals than in 2011, we believe it is still quite feasible for these group practices to meet the respective reporting threshold as this would be the reporting threshold should the members of the group practice choose to participate in the eRx Incentive Program as individual eligible professionals.

We invite public comment on the proposed criteria for determining successful electronic prescribers for eRx GPROs reporting for purposes of earning the 2012 and 2013 incentives.

(4) No Double Payments

We are prohibited from making double payments under section 1848(m)(3)(C)(iii) of the Act, which requires that payments to a group practice shall be in lieu of the payments that would otherwise be made under the eRx Incentive Program to eligible professionals in the group practice for being a successful electronic prescriber. Accordingly, consistent with 2010 and 2011, we propose to make incentive payments to group practices based on the determination that the eRx GPRO, as a whole, is a successful electronic prescriber for the respective program year. An individual eligible professional who is affiliated with a group practice participating in the eRx GPRO reporting option that meets the requirements of being a successful electronic prescriber under a group practice would not be eligible to earn a separate eRx incentive payment on the basis of the individual eligible professional meeting the criteria for successful electronic reporter at the individual level. We invite public comment on the proposed determination of the 2012 and 2013 incentive payment amount for group practices that are successful electronic prescribers.

Furthermore, we propose to make a technical change 42 CFR 414.92(g)(5)(ii) to modify ''another'' to ''a'' to clarify the provision.

h. The 2013 and 2014 Electronic Prescribing Payment Adjustments

As previously stated, for 2012, 2013, and 2014, if the eligible professional is not a successful electronic prescriber for the reporting period for the year, the PFS amount for covered professional services furnished by such professionals during the year shall be less than the PFS amount that would otherwise apply by—

- 1.0 percent for 2012;
- 1.5 percent for 2013; and
- 2.0 percent for 2014.

We propose to modify 42 CFR 414.92 to provide further explanation of the requirements for individual eligible professionals and group practices for the 2013 and 2014 payment adjustment, which we will propose below.

(1) Proposed Limitations to the 2013 and 2014 eRx Payment Adjustments—Individual Eligible Professionals

Whereas we believe that an incentive should be broadly available to encourage the widest possible adoption of electronic prescribing, even for low volume prescribers, we believe that a payment adjustment should be applied primarily to assure that those who have a large volume of prescribing do so electronically, without penalizing those for whom the adoption and use of an electronic prescribing system may be impractical given the low volume of prescribing. We propose that the 2013 and 2014 payment adjustments would not apply if:

- An eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant as of June 30, 2012, for purposes of the 2013 payment adjustment and June 30, 2013, for purposes of the 2014 payment adjustment. Since these eligible professionals do not generally prescribe, we have excluded these eligible professionals from the eRx Incentive Program.

For purposes of determining whether an eligible professional is an MD, DO, podiatrist, nurse practitioner, or physician assistant we would use National Plan and Provider Enumeration System (NPPES) data. It is an eligible professional's responsibility to ensure that his or her primary taxonomy code in NPPES is accurate. However, in 2011, we also established a G-code, (G8644) that eligible professionals can use to report to us that they do not have prescribing privileges. We propose to retain the reporting of this G-code for purposes of the 2013 and 2014 payment adjustments. For purposes of the 2013 payment adjustment, we propose that eligible professionals who report this G-code must do so on a claim with dates of services during the 6-month reporting period (January 1, 2012 and June 30, 2012). For purposes of the 2014 payment adjustment, we propose that eligible professionals who report this G-code must do so on a claim with dates of services during the 6-month reporting period (January 1, 2013 and June 30,

2013) so that we are able to distinguish whether a professional is reporting this G-code for the 2013 payment adjustment or the 2014 payment adjustment.

• The eligible professional's Medicare Part B allowed charges for covered professional services to which the electronic prescribing quality measure applies are less than 10 percent of the total Medicare Part B PFS allowed charges for all covered professional services furnished by the eligible professional during the respective payment adjustment reporting period. This is a required limitation under section 1848(m)(2)(B) of the Act. This calculation will be performed by dividing the eligible professional's total 2011 Medicare Part B PFS allowed charges for all such covered professional services submitted for the measure's denominator codes by the eligible professional's total Medicare Part B PFS allowed charges for all covered professional services (as assessed at the TIN/NPI level). If the result is 10 percent or more, then the statutory limitation will not apply. If the result is less than 10 percent, then the statutory limitation will apply. For the 12-month incentive and payment adjustment reporting periods, this calculation is expected to take place in the first quarter of the year following the reporting period (for example, in the first quarter of 2013 for the 12-month reporting period for the 2012 incentive). For the 6-month payment adjustment reporting period, this calculation is expected to take place within the calendar year for that 6-month reporting period (for example. within 2012 for the 6-month reporting period for the 2013 payment adjustment).

• An eligible professional who does not have at least 100 cases (that is, claims for patient services) containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during: The 6-month, 2013 payment adjustment reporting period (January 1, 2012 through June 30, 2012) for purposes of the 2013 payment adjustment or the 6-month, 2014 payment adjustment reporting period (January 1, 2013 through June 30, 2013) for purposes of the 2014 payment adjustment. If an eligible professional has less than 100 denominator-eligible instances in a 6-month period, this would be an indicator to us that the professional likely has a small Medicare patient population.

We invite public comment on the proposed limitations of the 2013 and 2014 payment adjustments.

(2) Proposed Requirements for the 2013 and 2014 eRx Payment Adjustments—Individual Eligible Professionals

As we explained previously, section 1848(a)(5) of the Act requires a payment adjustment be applied with respect to covered professional services furnished by an eligible professional in 2013 and 2014, if the eligible professional is not a successful electronic prescriber for the reporting period for the year. Section 1848(m)(3)(B) of the Act sets forth the requirements for being a successful electronic prescriber. However, section 1848(m)(3)(D) of the Act authorizes the Secretary to revise the criteria for submitting data on the electronic prescribing quality measure. In the 2011 PFS Final Rule with comment period, we established the same reporting criteria for being a successful electronic prescriber for purposes of the 2011 incentive and the 2013 payment adjustment, based on a 12-month reporting period in 2011 (75 FR 73565). In order to create another opportunity for an eligible professional to become a successful electronic prescriber for purposes of the 2013 payment adjustment, we propose the following criteria, based on the proposed 6-month reporting period, for being a successful electronic prescriber: An eligible professional will be deemed a successful electronic prescriber if he/she reports the electronic prescribing measure's numerator, that is, at least 1 prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system at least 10 times during the 6-month payment adjustment reporting period (that is, January 1, 2012 through June 30, 2012). Unlike the reporting criteria for the incentive payments where the numerator must be reported in connection with a denominator-eligible visit, for purposes of the 2013 and 2014 payment adjustments, we propose an eligible professional would be able to report the measure's numerator for any Medicare Part B PFS service provided during the reporting period, regardless of whether the code for such service appears in the denominator, because we recognize that eligible professionals may generate prescriptions during encounters that are not necessarily included in the measure's denominator.

For purposes of avoiding the 2014 payment adjustment, we also seek to provide more than one opportunity for eligible professionals to avoid the 2014 payment adjustment by becoming a successful electronic prescriber. Therefore, consistent with the finalized and proposed criteria for successful electronic prescribing for purposes of the 2013 payment adjustment, we propose that an eligible professional the following criteria for an eligible professional to be a successful electronic prescriber for purposes of the 2014 payment adjustment: (1) An eligible professional meets the criteria for the 2013 incentive, that is, reports that at least one prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system at least 25 times during the 12-month payment adjustment reporting period (that is, January 1, 2012 through December 31, 2012) or (2) An eligible professional reports the electronic prescribing measure's numerator (that is, that at least 1 prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system) at least 10 times during the 6-month payment adjustment reporting period (that is, January 1, 2013 through June 30, 2013).

As with the 2012 and 2013 incentive payments, we propose that the determination of whether an eligible professional is subject to the payment adjustment will be made at the individual professional level, based on the NPI and for each unique TIN/NPI combination. Tables 57 and 58 reflect the proposed criteria for being a successful electronic prescriber for an individual eligible professional for purposes of the 2013 and 2014 payment adjustment respectively.

TABLE 57—PROPOSED CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2013 ERX PAYMENT ADJUSTMENT FOR THE PROPOSED 6-MONTH REPORTING PERIOD—INDIVIDUAL ELIGIBLE PROFESSIONALS *

Reporting period	Criteria
6–month (Jan 1, 2012–Jun 30, 2012)	Report the electronic prescribing measure's numerator code at least 10 times.

* In the CY 2011 PFS final rule with comment period, we finalized a reporting criterion based on a 12-month reporting period (January 1, 2011 through December 31, 2011) for being a successful electronic prescriber for the 2013 payment adjustment. That is, the eligible professional becomes a successful electronic prescriber for the 2013 payment adjustment if, between January 1, 2011 and December 31, 2011 s/he reports on the 2011 electronic prescribing measure at least 25 times.

TABLE 58—PROPOSED CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2014 ERX PAYMENT ADJUSTMENT—INDIVIDUAL ELIGIBLE PROFESSIONALS

Reporting period	Criteria
12-month (Jan 1, 2012–Dec 31, 2012)	Report the electronic prescribing measure's numerator code at least 25 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2013 eRx incentive).
6-month (Jan 1, 2013–Jun 30, 2013)	Report the electronic prescribing measure's numerator code at least 10 times.

We proposed the previous criteria for being a successful electronic prescriber for purposes of the 2013 and 2014 payment adjustments because they are consistent with the criteria for being a successful electronic prescriber for purposes of the 2012 and 2013 payment adjustment that were finalized in the CY 2011 PFS final rule with comment period (75 FR 73562 through 73565). We invite public comment on the proposed criteria for becoming a successful electronic prescriber for the 2013 and 2014 payment adjustments for individual eligible professionals.

(3) Proposed Requirements for the 2013 and 2014 eRx Payment Adjustments—Group Practices

As required by section 1848(m)(3)(C) of the Act, we are also required to establish and have in place a process under which eligible professionals in a group practice shall be treated as a successful electronic prescriber for purposes of the payment adjustment. For purposes of the 2013 and 2014 payment adjustments, we propose that if a group practice chooses to participate in the eRx GPRO during CYs 2012 and 2013, respectively, then the group practice would be evaluated for applicability of the 2013 and 2014 payment adjustment as a group practice.

We propose an eRx GPRO will be deemed a successful electronic prescriber for purposes of the 2013 payment adjustment if, during the 6-month, 2013 payment adjustment reporting period (January 1, 2012 through June 30, 2012), a group practice reports the electronic prescribing measure's numerator (that is, that at least 1 prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system) at least 625 times (for group practices comprised of 25 to 99 eligible professionals) or 2,500 times (for group practices comprised of 100+ eligible professionals).

Similarly, for the 2014 payment adjustment, we propose the following: A group practice would be a successful electronic prescriber for purposes of the 2014 payment adjustment if the group practice meets the 2012 criteria for being a successful electronic prescriber for purposes of the 2012 incentive payment. In other words, the group practice would need to report the electronic prescribing measure's numerator for at least 625 (for group practices comprised of 25 to 99 eligible professionals) or 2,500 (for group practices comprised of 100 or more eligible professionals) times for encounters associated with at least 1 of the denominator codes that occur between January 1, 2012 and December 31, 2012. In addition, we propose that a group practice would also be a successful electronic prescriber for purposes of the 2014 payment adjustment if, during the 6-month, 2014 payment adjustment reporting period (January 1, 2013 through June 30, 2013), a group practice reports the electronic prescribing measure's numerator (that is, that at least 1 prescription for Medicare Part B PFS patients created during an encounter was generated and transmitted electronically using a qualified electronic prescribing system at least 625 times (for group practices with 25 to 99 eligible professionals) or 2,500 times (for group practices with 100+ eligible professionals)).

In addition, in accordance with the limitation under section 1848(m)(2)(B)(i) of the Act, the 2013 or 2014 payment adjustment would not apply to a group practice in which less than 10 percent of the group practice's estimated total allowed charges for the respective 6-month or 12-month payment adjustment reporting period are comprised of services which appear in the denominator of the 2012 or 2013 electronic prescribing measure. To be consistent with how this limitation is applied to group practices for purposes of the incentive, we propose to determine whether this limitation applies to a group practice for the payment adjustment at the TIN level. Tables 59 and 60 reflect the proposed criteria for being a successful electronic prescriber for a group practice for purposes of the 2013 and 2014 payment adjustments, respectively.

TABLE 59—PROPOSED CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2013 ERX PAYMENT ADJUSTMENT FOR THE PROPOSED 6-MONTH REPORTING PERIOD—GROUP PRACTICES

eRx GPRO Size	Reporting period	Criteria
25–99 Eligible Professionals	6-month (Jan 1, 2012–Jun 30, 2012)	Report the electronic prescribing measure's numerator code at least 625 times.
100+ Eligible Professionals	6-month (Jan 1, 2012–Jun 30, 2012)	Report the electronic prescribing measure's numerator code at least 2,500 times.

TABLE 60—PROPOSED CRITERIA FOR BEING A SUCCESSFUL ELECTRONIC PRESCRIBER FOR THE 2014 ERX PAYMENT ADJUSTMENT—GROUP PRACTICES USING THE ERX GPROS

eRx GPRO Size	Reporting period	Criteria
25–99 Eligible Professionals	12-month (Jan 1, 2012–Dec 31, 2012)	Report the electronic prescribing measure's numerator for at least 625 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 eRx incentive).
100+ Eligible Professionals	12-month (Jan 1, 2012–Dec 31, 2012)	Report the electronic prescribing measure's numerator for at least 2,500 times for encounters associated with at least 1 of the denominator codes (the same criteria as the 2012 incentive).
25–99 Eligible Professionals	6-month (Jan 1, 2013–Jun 30, 2013)	Report the electronic prescribing measure's numerator code at least 625 times.
100+ Eligible Professionals	6-month (Jan 1, 2013–Jun 30, 2013)	Report the electronic prescribing measure's numerator code at least 2,500 times.

We invite public comment on the proposed requirements for 2013 and 2014 electronic prescribing payment adjustment for eRx GPROs.

(4) 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.

(A) Proposed Significant Hardship Exemptions

In the CY 2011 PFS Final Rule with comment period (75 FR 73564 through 75 FR 73565), we finalized two circumstances under which an eligible professional or eRx GPRO can request consideration for a significant hardship exemption for the 2012 eRx payment adjustment:

- The eligible professional or eRx GPRO practices in a rural area with limited high speed internet access.
- The eligible professional or eRx GPRO practices in an area with limited available pharmacies for electronic prescribing.

For the 2013 and 2014 payment adjustments, we propose to retain these two significant hardship exemption categories. We propose that eligible professionals and eRx GPROs wishing to request applicability of these significant hardship exemption categories may do so via a web-based tool. Alternatively, since we created a G-code for each of the previous categories, we propose that eligible professionals and eRx GPROs may use the G-codes to request consideration for a significant hardship exemption for the 2013 and 2014 payment adjustment by reporting the appropriate G-code at least once on claims for services rendered during the respective 2013 and 2014 6-month reporting periods.

Since publication of the CY 2011 PFS Final Rule with comment period, we have received numerous requests to expand the categories under the significant hardship exemption for the payment adjustment. Some stakeholders have recommended specific circumstances of significant hardship for our consideration (for example, eligible professionals who have prescribing privileges but do not prescribe under their NPI, eligible professionals who prescribe a high volume of narcotics, and eligible professionals who electronically prescribe but typically do not do so for any of the services included in the electronic prescribing measure's denominator), while others strongly suggested we consider increasing the number of specific hardship exemption categories. We believe that many of the circumstances raised by stakeholders may pose a significant hardship and limit eligible professionals and group practices in their ability to meet the requirements for being successful electronic prescribers either because of the nature of their practice or because of the limitations of the electronic prescribing measure itself, and as a result, such professionals might be unfairly penalized. Therefore, in 2011, in the proposed rule entitled ''Proposed Changes to the Electronic Prescribing (eRx) Incentive'' (76 FR 31547), we proposed to expand the categories under the significant hardship exemption for the 2012 payment adjustment. Because we believe the reasons for proposing the expanded categories under the significant hardship exemption for the 2012 payment adjustment also apply to the 2013 and 2014 payment adjustments, we propose to retain the following significant hardship exemptions for the 2013 and 2014 payment adjustments:

- Inability to electronically prescribe due to local, state, or federal law or regulation
- Eligible professionals who prescribe fewer than 100 prescriptions during a 6-month, payment adjustment reporting period

(i) Inability to Electronically Prescribe Due to Local, State, or Federal Law or Regulation

We are proposing that, to the extent that local, State, or Federal law or regulation limits or prevents an eligible professional or group practice that otherwise has general prescribing authority from electronically prescribing (for example, eligible professionals who prescribe a large volume of narcotics, which may not be electronically

prescribed in some states, or eligible professionals who practice in a State that prohibits or limits the transmission of electronic prescriptions via a third party network such as Surescripts), the eligible professional or group practice would be able to request consideration for an exemption from application of the 2013 and/or 2014 payment adjustments, which would be reviewed on a case-by-case basis. We believe eligible professionals in this situation face a significant hardship with regard to the requirements for being successful electronic prescribers because while they may meet the 10 percent threshold for applicability of the payment adjustment, or the 100 denominator-eligible cases limit in a 6-month payment adjustment reporting period, they may not have sufficient opportunities to meet the requirements for being a successful electronic prescriber because Federal, State, or local law or regulation may limit the number of opportunities that an eligible professional or group practice has to electronically prescribe.

(ii) Eligible Professionals Who Prescribe Fewer Than 100 Prescriptions During a 6-Month, Payment Adjustment Reporting Period

We are proposing that an eligible professional who has prescribing privileges but prescribes fewer than 100 prescriptions during a 6-month, payment adjustment reporting period (for example, a nurse practitioner who may not write prescriptions under his or her own NPI, a physician who decides to let his Drug Enforcement Administration registration expire during the reporting period without renewing it, or an eligible professional who prescribed fewer than 100 prescriptions between January 1, 2012 and June 30, 2012 regardless of whether the prescriptions were electronically prescribed or not), yet still meets the 10 percent threshold for applicability of the payment adjustment, would be able to request consideration for a significant hardship exemption from application of the 2013 and/or 2014 payment adjustment, which would be reviewed on a case-by-case basis. We believe that it is a significant hardship for eligible professionals who have prescribing privileges, but infrequently prescribe, to become successful electronic prescribers because the nature of their practice may limit the number of opportunities an eligible professional or group practice to prescribe, much less electronically prescribe.

We invite public comments on our proposal to modify 42 CFR 414.92 to include our proposed significant hardship exemption categories for the 2013 and 2014 payment adjustments.

As we realize that the 4 significant hardship exemptions we have proposed above may not capture every circumstance that could constitute a significant hardship, we invite public comment on other suggestions for significant hardship exemption categories that we may want to consider.

(B) Process for Submitting Significant Hardship Exemptions—Individual Eligible Professionals and Group Practices

To request a significant hardship exemption for any of the categories proposed and previously described, we are proposing that an eligible professional provide to us by the end of the 2013 and/or 2014 payment adjustment reporting periods (that is June 30, 2012 for the 2013 payment adjustment and June 30, 2013 for the 2014 payment adjustment), the following:

- The name of the practice and other Identifying information (for example: TIN, NPI, mailing address, and e-mail address of all affected eligible professionals.
- The proposed significant hardship exemption category(ies) that apply.
- A justification statement describing how compliance with the requirement for being a successful electronic prescriber for the respective 2013 and/or 2014 payment adjustment during the reporting period would result in a significant hardship to the eligible professional.
- An attestation of the accuracy of the information provided.

The justification statement should be specific to the category under which the eligible professional or group practice is submitting its request and must explain how the exemption applies to the professional. For example, if the eligible professional is requesting a significant hardship exemption due to Federal, State, or local law or regulation, he or she must cite the applicable law and how the law restricts the eligible professional's ability to electronically prescribe. CMS will review the information submitted by each eligible professional on a case-by-case basis. In addition, we are proposing that an eligible professional or group practice must, upon request, provide additional supporting documentation if there is insufficient information (such as, but not limited to, a TIN or NPI that we cannot match to the Medicare claims, a certification number for the Certified EHR Technology that does not appear on the list of Certified EHR Technology, or an incomplete justification for the significant hardship exemption request) to justify the request or make the determination of whether a significant hardship exists.

We also are proposing that eligible professionals or group practices would be able to submit significant hardship exemption requests using the web-based tool or interface (that we also proposed to use in the 2011 ''Proposed Changes to the Electronic Prescribing (eRx) Incentive Program'' proposed rule). Under the web-based tool, we propose that eligible professionals and group practices be able to log-in, request a specific significant hardship exemption, and provide the reasons why a significant hardship exemption should apply. We propose that eligible professionals would be required to submit their requests for a significant hardship exemption via the web-based tool during the relevant 6-month payment adjustment reporting period. For example, if an eligible professional is requesting a significant hardship exemption from the 2013 payment adjustment, then the request must be submitted between January 1, 2012 and June 30, 2012.

We also are proposing that once we have completed our review of the eligible professional's or group practice's request and made a decision, we would notify the eligible professional or group practice of our decision and all such decisions would be final. Eligible professionals or group practices would not have the opportunity to request reconsiderations of their requests for significant hardship exemption. We invite public comment on the proposed process for individual eligible professionals and group practices for submitting these requests for significant hardship exemptions to us (including comments on the type of information we are proposing eligible professionals must submit, the proposed options for how the information could be submitted, and the proposed timeframes for submission).

G Physician Compare Web Site

1. Background and Statutory Authority

Section 10331 (a)(1) of the Affordable Care Act (42 U.S.C. 1395w–5 note) requires that we, by no later than January 1, 2011, develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act as well information on other eligible professionals who participate in the Physician Quality Reporting System under section 1848 of the Act (42 U.S.C. 1395w–4). Public

reporting of performance results on standardized quality measures currently exists on *http://www.medicare.gov* for the following:

- Hospitals (Hospital Compare).
- Dialysis facilities (Dialysis Facility Compare).
- Nursing homes (Nursing Home Compare).
- Home health facilities (Home Health Compare).

As an initial step towards providing information on the quality of care for services furnished by physicians and other professionals to Medicare beneficiaries, we have enhanced the existing Physician and Other Health Care Professionals directory at *http://www.medicare.gov* to develop a similar Compare Web site specific to physicians and other professionals. In accordance with section 10331 of the Affordable Care Act, we launched the first phase of the Physician Compare Internet Web site 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.

2. Proposed Plans

Section 10331 (a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and with respect to reporting periods that begin no earlier than January 1, 2012, we implement a plan for making information on physician performance publicly available through the Physician Compare Web site. 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 publically 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 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. In developing the plan for making information on physician performance publicly available through the Physician Compare Web site, 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 the Physician Compare Web site developed, 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 to foster transparency and public reporting by 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 Web site to publicly report physician performance results.

For purposes of implementing a plan to publicly report physician performance, we plan to use data reported under the existing Physician Quality Reporting System as an initial step for making public physician ''measure performance'' information on Physician Compare. By ''measure performance,'' 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.

The Physician Quality Reporting System is a readily available source of measures performance data. First implemented in 2007, the program grew to include 194 different measures in 2011. The measures used in the Physician Quality Reporting System cover a wide range of health conditions and topics and include measures applicable to most physician specialties and other clinicians. Work is underway to ensure consistency of quality measures reported under the Physician Quality Reporting System and the EHR Incentive Program.

The first phase of the plan to make information on physicians and other eligible professionals who participate in the Physician Quality Reporting System publically available was completed through the launch of the Physician Compare Web site and the posting of the names of those eligible professionals who satisfactorily participated in the Physician Quality Reporting System.

During the second phase of the plan, occurring in 2011 through 2012, we will continue to work towards the development and improvement of the Web site. Our plans for Physician Compare Web site development during this second phase include monthly data refreshes and a semiannual Web site release to incorporate updates and improvements to the Web site. Updates will include the addition of the names of eligible professionals who are successful electronic prescribers, as required by section 1848(m)(5)(G) of the Social Security Act (the Act), as well as the names of those eligible professionals who participate in the EHR Incentive Program, as required by section 1848(o)(3)(D) of the Act. Additional enhancements planned include the addition of links to specialty board Web sites that can provide more information

on an eligible professional's board certification status and improved Web site functionality and layout.

Moving towards the reporting of physician performance information, we propose to take an initial step by making public the performance rates of the quality measures that group practices submit under the 2012 Physician Quality Reporting System group practice reporting option (GPRO) described in section IV.F.b.2. of this proposed rule. We also propose to publicly report the performance rates of the quality measures that the group practices participating in the Physician Group Practice demonstration report on the Physician Compare Web site as early as 2013 for performance information collected in CY 2012. Subject to the discussion later in this section, we would make public the measure performance for each of the measures included in the 2012 Physician Quality Reporting System GPRO. Since the quality measures in GPRO are reported for the group as a whole, the information on measure performance would also apply to the group as a whole, rather than to individual physicians within a group.

Public reporting of the group practices' measure performance results at the group practice level would begin public reporting at the earliest time specified by the statute. We believe the design of the GPRO (see section IV.F.b.2. of this proposed rule) facilitates making public groups' performance results. All groups participating in the GPRO would be reporting on the same set of clinical quality measures, which allows for comparison of the results across groups.

To eliminate the risk of calculating performance rates based on a small denominator, we propose to set a minimum patient sample size threshold. A minimum threshold of 25 patients will have to be met in order for the group practice's measure performance rate to be reported on the Physician Compare Web site. If the threshold of 25 patients is not met for a particular measure, the group's performance rate for that measure would be suppressed and not publically reported. In determining the minimum patient sample size, we took into consideration the minimum patient sample size used by other Compare Web sites that publically report measure performance data. We wanted to ensure that we used a number large enough to accurately reflect measure performance, but not so large that it will limit the number of groups for which measure performance could be reported. In taking into consideration the minimum patient sample size used by other Compare Web sites that publically report measure performance data, we also considered a minimum patient sample size of 10 patients, 20 patients and 30 patients. As we are proposing to report measure performance at a group level and a majority of the other Compare Web sites use minimum sample sizes of between 20 and 30 patients, we concluded that a minimum patient sample size of 25 would meet our criteria.

As discussed in section IV.F.b.2 of this proposed rule, we propose that group practices participating in the 2012 Physician Quality Reporting System GPRO would agree in advance to have their reporting performance results publicly reported as part of their self-nomination to participate in the 2012 Physician Quality Reporting System GPRO. Finally, we propose to modify the GPRO data collection tool for 2012 to calculate the numerator, denominator, and measure performance rate for each measure from the data that the group practices use to populate the tool and provide each group practice this information at the time of tool submission. This feature would allow the group practice the opportunity to review their measure performance results before they are made public in accordance with section 10331(b) of the Affordable Care Act. For groups reporting using GPRO information that is made public in 2013, we do not propose to post information with respect to the measure performance of individual physicians or eligible professionals associated with the group. However, we propose to identify the individual eligible professionals who were associated with the group during the reporting period. We will identify the eligible professionals associated with the group by posting a list of the eligible professionals on the Physician Compare Web site.

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 proposal to: (1) To publicly report group practices' measure performance results in 2013 based on group practices' 2012 Physician Quality Reporting System performance results under GPRO; and (2) utilize a minimum patient sample size of 25 for reporting and displaying measure performance on the Physician Compare Web site.

H. Medicare EHR Incentive Program for Eligible Professionals for the 2012 Payment Year

1. Background

On July 28, 2010, we published in the **Federal Register** (75 FR 44314) a final rule entitled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' to implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) that amended sections 1848, 1853, and 1886 of the Social Security Act (the Act) to provide incentive payments to eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid programs that successfully adopt, implement, upgrade, or demonstrate meaningful use of certified electronic health record (EHR) technology. In that final rule, we specified the initial criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, including the initial clinical quality measures (CQMs) for which these providers would be required to submit information to the Secretary in the form and manner specified by CMS.

In the July 28, 2010 final rule (75 FR 44430), we stated that for the Medicare EHR Incentive Program, for the 2011 payment year, EPs, eligible hospitals, and CAHs will be required to submit CQM results as calculated by certified EHR technology through attestation, and for the 2012 payment year and subsequent payment years, they will be required to electronically submit CQM results as calculated by certified EHR technology. Additionally, we stated that the primary method for these providers to report required CQM information electronically will be to submit data by an upload process through a CMS-designated portal. In the final rule, we also stated that we anticipated that we would have completed the necessary steps to have the capacity to receive information on CQMs electronically for the 2012 payment year. However, we also stated that if the Secretary does not have the capacity to accept the information on CQMs electronically in 2012, consistent with sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, then we will continue to rely on attestation for reporting CQMs as a requirement for demonstrating meaningful use of certified EHR technology for the 2012 payment year (75 FR 44380).

We also stated in the final rule that certified EHR technology will be required to calculate the clinical quality measure results and transmit under the Physician Quality Reporting Initiative (PQRI) Registry XML specification (75 FR 44435). Since the publication of the final rule, we have determined that it is not feasible to receive electronically the information necessary for clinical quality measure reporting based solely on the use of PQRI 2009 Registry XML Specification content exchange standards as is required for certified EHR technology. This is because the specification is tailored to the elements required for 2009 PQRI Registry submission, rather than constituting a more generic standard. As a result, we propose to modify the requirement that clinical quality measure reporting must be done electronically. Specifically, we propose that for the 2012 payment year, EPs may continue to report clinical quality measure results as calculated by certified EHR technology by attestation, as for the 2011 payment year.

In addition to attestation, we propose to establish a pilot mechanism through which EPs participating in the Medicare EHR Incentive Program may report CQM information electronically using certified EHR technology for the 2012 payment year. Participation in the pilot would be voluntary and would enable EPs to satisfy the Medicare EHR Incentive Program requirements for reporting CQMs for the 2012 payment year. EPs who choose not to participate in the pilot would be able to continue to use an attestation methodology for reporting CQMs for payment year 2012.

We propose to modify 42 CFR 495.8(a)(2) by adding a new paragraph to allow for the reporting of CQMs for the Medicare EHR Incentive Program via the Physician Quality Reporting System-Medicare EHR Incentive Pilot. Furthermore we are proposing to revise 42 CFR 495.8(a)(2)(ii) by deleting the word ''electronically'' and adding the words ''form and'' such that it reads as follows:

Reporting of clinical quality information. For 42 CFR 495.6(d)(10), 'Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States,' report the ambulatory clinical quality measures selected by CMS to CMS (or in the case of Medicaid EPs, the States) in the form and manner specified by CMS (or in the case of Medicaid EPs, the States).

2. The Proposed Physician Quality Reporting System-Medicare EHR Incentive Pilot

We propose to modify 42 CFR 495.8(a)(2) to indicate that EPs participating in the Medicare EHR Incentive Program can meet the CQM reporting requirements of the EHR Incentive Program for payment year 2012 by participating in a pilot, which we refer to as the Physician Quality Reporting System-Medicare EHR Incentive Pilot. Sections 1848(o)(2)(B)(ii) of the Act provides authority for the Secretary to accept information on CQMs electronically on a pilot basis. We propose that EPs may participate in the pilot on a voluntary basis, and that those EPs who choose not to participate may instead continue to attest to the results of the CQMs as calculated by certified EHR technology, consistent with the CQM reporting method for the 2011 payment year. However, we encourage participation in the pilot based on our desire to adequately pilot electronic submission of CQMs and to move to a system of reporting where EPs can satisfy the CQM reporting requirements for both the Physician Quality Reporting System and the EHR Incentive Program. To participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, we propose that EPs would be required to electronically report the CQMs using certified EHR technology via one of two options that are based on the existing reporting platforms of the Physician Quality Reporting System. As described later in this section, one option would be based on the infrastructure used for the Physician Quality Reporting System EHR data submission vendor reporting mechanism. The second option would be based on the infrastructure used for the Physician Quality Reporting System EHR reporting mechanism. EPs who seek to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot must also participate in the Physician Quality Reporting System itself, because the pilot will rely on the infrastructure used for Physician Quality Reporting System.

To move towards the integration of reporting on quality measures under the Physician Quality Reporting System with the reporting requirements of the Medicare EHR Incentive Program, as required by section 1848(m)(7) of the Act (''Integration of Physician Quality Reporting and EHR Reporting''), we propose that participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would require EPs to submit information on the same CQMs that were adopted for EPs for the Medicare EHR Incentive Program and included in Tables 6 and 7 of the July 28, 2010 final rule (75 FR 44398 through 44410). We propose that EPs participating in this pilot must submit information on the three core measures included in Table 7, up to three of the alternate core measures included in Table 7 insofar as the denominator for one or more of the core measures is zero, and three additional measures from the measures included in Table 6, as is otherwise required by the final rule to successfully demonstrate meaningful use (75 FR 44409 through 44411). EPs that elect to participate in this Physician Quality Reporting System-Medicare EHR Incentive Pilot will still be required to report information on the CQMs as required under the Stage 1 criteria established for the Medicare EHR Incentive Program regardless of which option they select as described later in this section. As the reporting of CQMs is only one of the 15 core meaningful use objectives for EPs for the Medicare EHR Incentive Program, an EP who elects to participate in the proposed Physician Quality Reporting System-Medicare EHR Incentive Pilot would still be required to meet and attest to the remaining 14 core objectives and required menu set objectives using the attestation module on the CMS Web site for the program. Consequently, participation in this pilot only applies to the method of reporting for meeting the meaningful use CQM objective in the EHR Incentive Program (42 CFR 495.6(d)(10)).

To participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot, we propose EPs would be required to electronically report the CQMs by choosing one of the options described later in this section. By submitting the required information through the pilot, an EP could meet the core objective for reporting CQMs for the Medicare EHR Incentive Program for the 2012 payment year. After attesting to all other meaningful use objectives, the EP's attestation file would be placed in a holding status, with respect to the CQM objective only, until the EP reports the CQMs via one of the proposed Physician Quality Reporting System-Medicare EHR Incentive Pilot options. Thus, the EP would not know if he/she successfully met the requirements for the Medicare EHR Incentive Program with respect to the CQM objective until the CQMs are received at the end of the submission period for measures for the Physician Quality Reporting System (we expect this would be 2 months after the close of the reporting period, which is the CY 2012, and no later than February 29, 2013). As explained later in this section, any EP participating in this pilot would be required to report CQMs based on a full calendar year, regardless

of the EP's year of participation in the Medicare EHR Incentive Program.

If the EP who selects one of the pilot options subsequently determines completion of the pilot is unfeasible, then we propose it is permissible for the EP to go back into the Medicare EHR Incentive Program attestation module on the CMS Web site and complete attestation for the CQMs assuming it is within the reporting timeframes established under the EHR Incentive Program. We note that EPs who are in their first year of participation in the EHR Incentive Program and choose to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot only will have their EHR incentive payments delayed until the data submitted under the Pilot has been analyzed. However, participation in this Physician Quality Reporting System-EHR Incentive Pilot will allow for the receipt of EHR Incentive Program and Physician Quality Reporting System incentives, provided an EP meets the provisions described later in this section.

a. EHR Data Submission Vendor-Based Reporting Option

As discussed further in the Physician Quality Reporting System section IV.F.1(d).(3).(b). of this proposed rule, EPs participating in the Physician Quality Reporting System may choose to report the Physician Quality Reporting System measures to CMS via a Physician Quality Reporting System qualified EHR data submission vendor. For purposes of the Physician Quality Reporting System, a Physician Quality Reporting System qualified EHR data submission vendor would receive data from an EP's EHR and subsequently reformat and transmit the data on behalf of the EP to CMS. Under this reporting option, we propose that an EP participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would submit CQM data from his or her certified EHR technology to a Physician Quality Reporting System qualified EHR data submission vendor. We expect to post a list of the 2012 Physician Quality Reporting System EHR data submission vendors that are qualified to submit data from an EP's certified EHR technology to CMS on the EP's behalf on the Physician Quality Reporting System section of the CMS Web site (*http://www.cms.gov/pqrs*) by summer 2012.

Under this option, the Physician Quality Reporting System qualified EHR data submission vendor would obtain data elements for the calculation of CQMs from the EP's certified EHR technology and then submit the calculated results to CMS on the EP's behalf via a secure portal. As discussed previously, in order for an EP to submit CQMs electronically through the Physician Quality Reporting System-Medicare EHR Incentive Pilot EHR data submission vendor-based reporting option, we propose that such EPs must submit information on the same CQMs as required by the July 28, 2010 final rule, which must be based on data contained in the EP's certified EHR technology. However, it would be sufficient for an EP participating in this EHR data submission vendor-based reporting option to submit CQM data as required by the pilot even though such data would differ from what is required by the July 28, 2010 final rule in the following two respects: (1) The data would be limited to Medicare patients rather than all patients, and (2) the data would be based on a CQM reporting period of 1-calendar year regardless of which year of participation in the Medicare EHR Incentive Program the EP is in (resulting in a later determination of whether the EP has successfully demonstrated meaningful use, for those EPs in their first year of program participation). We invite comment on the proposed EHR data submission vendor-based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

b. EHR-Based Reporting Option

As discussed further in the Physician Quality Reporting System section IV.F.1.(d).(3).(a). of this proposed rule, EPs participating in the Physician Quality Reporting System via the EHR reporting mechanism can choose to report the Physician Quality Reporting System measures to CMS directly from the EP's EHR. Therefore, under this EHR-Based reporting option, we propose that an EP participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would submit CQM data directly from his or her certified EHR technology to CMS via a secure portal using the infrastructure of the Physician Quality Reporting System EHR reporting mechanism. We propose that in order to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot under this option, the EP's certified EHR technology must also be a 2012 Physician Quality Reporting System qualified EHR. We expect to post a list of the 2012 Physician Quality Reporting System qualified EHRs on the Physician Quality Reporting System section of the CMS Web site prior to January 1, 2012. Due to this proposed Physician Quality Reporting System-Medicare EHR Incentive Pilot, we are proposing to have an additional vetting process for EHR vendors wishing to participate in the Pilot. We expect to post an additional list of these additional 2012 qualified EHR vendors, if applicable, and their products in the summer of 2012.

As discussed previously, in order for an EP to submit CQMs electronically through the Physician Quality Reporting System-Medicare EHR Incentive Pilot EHR-Based reporting option, we propose that such EPs must submit information on the same CQMs as required by the July 28, 2010 final rule, which must be based on data contained in the EP's certified EHR technology. That is, EPs participating in this pilot must submit information on the three core measures included in Table 7, up to three of the alternate core measures included in Table 7 insofar as the denominator for one or more of the core measures is zero, and three additional measures from the measures included in Table 6, as is otherwise required by the final rule to successfully demonstrate meaningful use. If the EP cannot report three additional measures without zero denominators, the EP must report on all applicable measures (that is, 1 or 2 measures) and attest that all remaining measures have zero denominators. However, as with the EHR data submission vendor-based reporting option, the data would be different from what is required by the July 28, 2010 final rule in that it would be: (1) Limited to Medicare patients rather than all patients; (2) patient-level data from which we may calculate CQM results using a uniform calculation process, rather than aggregate results calculated by the EP's certified EHR technology; and (3) based on a CQM reporting period of 1 calendar year regardless of the EP's year of participation in the Medicare EHR Incentive Program (resulting in a later determination of whether the EP has successfully demonstrated meaningful use, for those EPs in their first year of program participation). We invite comment on the proposed EHR-Based reporting option under the Physician Quality Reporting System-Medicare EHR Incentive Pilot.

In addition, as discussed in the Physician Quality Reporting System section of this proposed rule, we propose if an EP successfully submits all required CQM data from certified EHR technology, which also must be a Physician Quality Reporting System qualified EHR product, directly to CMS, then the EP would also meet the criteria for satisfactory reporting under the 2012 Physician Quality Reporting System, which would also qualify the EP under

the 2012 Physician Quality Reporting System.

The Medicare EHR Incentive Program measures, including the core and alternate core measures, and the 38 additional measures, are specified in the Physician Quality Reporting System's Table 31 of this proposed rule. It should be noted that while the EP is required to use certified EHR technology, the electronic submission format used for this pilot is not a functionality of certified EHR technology. Rather, for purposes of the pilot, the certified EHR technology must conform to the qualifications for an EHR under the Physician Quality Reporting System.

3. Method for EPs To Indicate Election To Participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot for Payment Year 2012

EPs electing to participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot would be able to indicate their intent to fulfill the CQM objective by participating in the Physician Quality Reporting System-Medicare EHR Incentive Pilot under the EHR Incentive Program attestation module. The EHR Incentive Program attestation module is available on the CMS Web site at *https://www.cms.gov/EHRIncentivePrograms/32_Attestation.asp#TopOfPage.*

I. Improvements to the Physician Feedback Program and Establishment of the Value-Based Payment Modifier (Effect of Sections 3003 and 3007 of the Affordable Care Act on the Program)

1. Overview

The requirements of the Physician Feedback Program, in section 1848(n) of the Act, as amended by section 3003(a) of the Affordable Care Act, and the value-based payment modifier (''value modifier''), under section 1848(p) of the Act, as added by section 3007 of the Affordable Care Act, mutually reinforce our goal to provide physicians with fair, actionable and meaningful information concerning resource use and quality regarding their Medicare fee-for-service patients. We view value-based purchasing (''VBP'') as an important step toward revamping not only how care and services are paid for, but also moving increasingly toward rewarding better value, outcomes and innovations instead of volume. The approach used this year and that we anticipate using in future years for the Physician Feedback reports will serve as the testing basis to develop and implement the value modifier, which will be applied to certain physicians and physician groups under the physician fee schedule starting in 2015.

In 2011, we will begin to include the quality measures that are reported in the Physician Quality Reporting System in the Physician Feedback reports. Aligning quality measures reduces potential program inconsistencies, ensures we do not measure the same clinical process or outcome using different data sources or methodologies, and does not place new reporting burdens on physicians. For physicians who participate in the Physician Quality Reporting System, it also identifies clear and consistent opportunities for improvement, because the Feedback reports will show how their performance compares to their peers on the same quality measures.

Under section 1848(p)(4)(B) of the Act, we are required to begin implementing the value modifier through the rulemaking process during 2013, so that it is ready for application to specific physicians and groups of physicians under the physician fee schedule in 2015. We expect the value modifier to evolve after its initial application in 2015. We anticipate that information we have obtained from the Physician Feedback reports, our efforts to learn from and build upon the best transparent practices and methodologies developed in the private sector, and our continued and sustained dialogue with the physician and patient communities will yield significant improvements to the development of the value modifier. We plan to move forward with substantial input from physicians and experts as we continue to develop and implement these programs.

2. Background

As required under section 1848 (n) of the Act, as added by section 131(c) of the Medicare Improvements for Patients and Providers Act and amended by section 3003(a) of the Affordable Care Act, we established and implemented by January 1, 2009, the Physician Resource Use Measurement & Reporting Program (now referred to as the Physician Feedback Program) (74 FR 61844). The purpose of the Physician Feedback Program is to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 1848(n) of the Act also authorized us to include information on the quality of care furnished to Medicare beneficiaries by a physician or group of physicians. We have completed two phases of Physician Feedback reports and, by the end of 2011, we intend to implement Phase III of the Physician Feedback Program, by providing reports on both resource use and quality measures that cover a larger number and increased breadth of physicians and groups of physicians.

Phase I was discussed in the CY 2010 PFS proposed and final rules (74 FR 33589 and 74 FR 61844, respectively). In Phase I, we sent to several hundred individual practicing physicians in 12 geographic areas reports that contained per capita and episode-based cost information based on 2007 claims.[1] In creating these reports, we assessed patient attribution models and risk adjustment methodologies. We also tested various report designs with practicing physicians.

In Phase II of the Physician Feedback Program, we expanded on Phase I by providing reports that included quality measures for both individual and groups of physicians in the same 12 geographic areas using the same 2007 claims data. (Phase II was discussed in the CY 2011 PFS proposed and final rules 75 FR 40113 and 75 FR 73377, respectively). The quality measures used were the claims-based measures developed by us in the Generating Medicare Physician Quality Performance Measurement Results (GEM) project (74 FR 61846).[2] This initial core set of 12 quality measures was a first step to provide sufficient quality information to allow peer group comparisons. These measures were calculated using administrative claims data and did not require physicians to submit additional quality data. The measures captured several chronic conditions that are prevalent in the Medicare population and could be applied to all eligible physicians, although the measures were most applicable to primary care physicians.

Phase II reports contained total per capita cost information, as well as total per capita cost information for those beneficiaries with the following five common chronic diseases: (1) Diabetes; (2) congestive heart failure; (3) coronary artery disease; (4) chronic obstructive pulmonary disease; and (5) prostate cancer. This information was not limited to the cost of treating the disease itself, but also included total Parts A and B per capita cost information, as well as service category breakdowns, for the care received by the subset of attributed beneficiaries with that disease. Phase II reports did not include episode-specific cost information (as we had included in the Phase I reports),

[1] The 12 geographic areas are: Boston, MA, Syracuse, NY, Northern New Jersey, Greenville, SC, Miami, FL, Little Rock, AR, Indianapolis, IN, Cleveland, OH, Lansing, MI, Phoenix, AZ, Seattle, WA, and Orange County, CA.

[2] *http://www.cms.gov/GEM.*

because we found that the two commercially available proprietary groupers, which were not built for use with Medicare claims data, did not work well to create episodes for the significant number of Medicare beneficiaries with multiple chronic conditions (75 FR 73378).

We provided Phase II reports to 36 group practices and approximately 1,650 individual physicians who were members of these practices in the 12 geographic areas identified in Phase I. A group was defined as a single provider entity, identified by its tax identification number (TIN), which served at least 5,000 Medicare beneficiaries and in which at least one primary care physician and at least one medical specialist or surgeon in the group billed for Evaluation and Management (E/M) Medicare services. The use of group reports allowed for more robust comparisons on a fuller set of quality measures, because the groups were more likely to have sufficient number of cases to calculate each measure.

We used a ''single-provider plurality-minimum [3]'' method to attribute beneficiaries to the 36 group practices and the individual physicians. This method was based on the highest number of E/M services furnished by an individual physician and a minimum threshold of 20 percent of E/M costs.[4] Attribution of a beneficiary to a group practice was based on the group practice that provided the plurality of E/M services and a minimum threshold of 30 percent of E/M costs. For both individuals and groups, we required at least 30 beneficiaries to be assigned to either the individual or the group practice.[5] Seventy percent of eligible beneficiaries were attributed to an individual physician or group practice. These beneficiaries accounted for 53 percent of total Parts A and B costs but covered only 30 percent of individual physicians.

Our data analysis showed that the single-provider plurality-minimum rule generally assigned Medicare beneficiaries correctly to primary care physicians including internists, geriatricians, family practitioners, and general practitioners. However, this rule did not work well to attribute beneficiaries with multiple conditions that see a variety of physicians, because a single physician was unlikely to have both provided the plurality of E/M visits and to have also accounted for 20 percent of E/M costs.

As in Phase I, we price standardized the cost data to adjust for geographic differences. We also employed the same method of risk adjustment for per capita costs as we use in the Medicare Advantage (MA) program; that is, the hierarchal condition category (HCC) model for the cost data.[6] We did not risk-adjust the quality data included in Phase II, because the GEM measures are all clinical process measures, measure specifications provided detailed inclusion/exclusion criteria, and it is generally accepted that these measures need not be risk adjusted.

The individual-level reports in both phases of the program contained two peer group comparisons: (1) Physicians in the same specialty in the same geographic area; and (2) physicians in the same specialty across all 12 geographic areas. Peer group comparisons were made for both measures of cost and quality. We imposed a minimum peer group size of 30 physicians in Phase II for each of the cost and quality measures to ensure the group comparisons were credible to the physicians being compared. For the per capita cost measures, the physician was shown his or her position in a distribution that specifically identified the 10th, 50th, and 90th percentiles of performance.

3. Future Considerations for Phase III Physician Feedback Program

a. Phase III Physician Feedback Reports (Fall 2011)

Based on the experience gained so far and our plan to provide reports to a greater number and percentage of physicians, we intend to increase production and dissemination of Physician Feedback reports. In 2011, we are examining several approaches to developing and disseminating reports based on our 2010 experience. We believe that many of the issues we address in these reports will assist us as we begin to implement the value modifier in 2013.

We anticipate using quality measures reported in the Physician Quality Reporting System in the Physician Feedback reports this year. We further believe that use of these measures will begin to reduce potential program inconsistencies, ensure we do not measure the same clinical process or outcome using different data sources or methodologies, and not place new reporting burdens on physicians. In addition, elsewhere in this proposed rule, we are proposing to align the quality measures in the Physician Quality Reporting System with the Electronic Health Records incentive program quality measures. We seek comment on using the performance data in the Physician Quality Reporting System in the Physician Feedback program and on other issues discussed below that could help inform future phases of the Physician Feedback program.

(1) Physician Group Reports

We intend to create physician feedback reports for the 35 large medical group practices (each with 200 or more physicians) that chose to participate in the Physician Quality Reporting System Group Practice Reporting Option (GPRO–1) in 2010. We specifically chose these medical groups, because they could be compared on the common set of 26 quality measures included in the GPRO–1 reporting tool. The reports will be e-mailed to each group. We anticipate scheduling outreach and feedback sessions following dissemination of these reports to garner physician reaction to the information contained in the reports and elicit physician input on ways to increase their utility in future years.

The resource use portion of these reports will present summary information based on 2010 Medicare Parts A and B paid claims for all Medicare providers paid under the PFS who treated patients attributed to a participating medical practice group. This information will allow each group to compare its per capita Medicare costs to the per capita Medicare costs attributed to all 35 medical practice groups that participated in the 2010 GPRO–1 cohort. In addition, the report will show each medical group its average per capita costs for various types of fee-for-service patient services. The reports will also display group-specific data on per capita costs and hospital utilization of patients who have chronic conditions such as diabetes, heart failure, COPD, and coronary artery disease. Data in these reports will be risk adjusted and price standardized in a similar manner to the Phase II reports.

[3] Under a ''single-provider plurality-minimum'' attribution method, a beneficiary is attributed to the one physician who furnished the plurality of the beneficiary's E/M services during the year so long as that physician billed at least 20 percent of the beneficiary's E/M allowed charges for the year. If a beneficiary did not receive the plurality of services from the same physician that met the 20 percent minimum, the beneficiary was not assigned to a physician. For a more detailed discussion of methodology issues, see the Detailed Methodology Specification, available at *https://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_QRUR_Detailed_Methodology.pdf.*

[4] Costs refer to allowed charges for Part A and B services.

[5] We chose 30 beneficiaries because this threshold is commonly used for attribution purposes.

[6] For more information about hierarchal condition categories model, see *https://www.cms.gov/MedicareAdvtgSpecRateStats/downloads/Evaluation_Risk_Adj_Model_2011.pdf.*

The quality portion of these reports will present the group's performance on each of the 26 quality measures included in the Physician Quality Reporting System 2010 GPRO–1 reporting option. It will also show the average rate of preventable hospital admissions (for which a lower rate is better) for six ambulatory care-sensitive conditions: Diabetes, bacterial pneumonia, dehydration, chronic obstructive pulmonary disease (COPD), urinary tract infection, and congestive heart failure. The information presented will also allow each group to compare its performance to the performance of all of the 35 medical practice groups that participated in the 2010 GPRO–1 cohort.

(2) Reports to Individual Physicians

Late in 2011, we also intend to disseminate Physician Feedback reports to physicians paid under the PFS within four states: Iowa, Kansas, Missouri, and Nebraska. We choose these four states because the Medicare Administrative Contractor (MAC) serving these states can assist us in e-mailing these reports to a substantial number of physicians because of its robust electronic communications infrastructure. There are approximately 56,000 physicians in these four states. We realize, however, that we will not produce reports for all of these physicians, because some portion of the total will not have sufficient numbers of fee-for-service Medicare patients to qualify for a report based on the attribution rules we use. As discussed later in this section, we are examining which attribution rules to apply to these individual reports.

Individual physicians in these four States who satisfactorily reported data on quality measures under the Physician Quality Reporting System will receive a report that includes their performance on these quality measures. In addition, individual reports will display clinical quality measures that are derived from Medicare claims for all physicians in these four States. We used an internal multi-step process among our medical officers (who represent a variety of medical specialties) and other internal experts to identify these claims-based quality measures. Our medical officers and internal experts thoroughly reviewed over 70 claims-based National Quality Forum-endorsed measures and ultimately recommended 28 claims-based clinical measures to include in the 2011 individual physician reports. These measures include the 12 HEDIS measures that CMS included in the 2010 reports. Use of these 28 measures in the 2011 reports will allow us to have a sufficient number of cases to make peer group comparisons, which we believe are a critical component of the Physician Feedback program. The claims-based clinical measures for the 2011 individual physician feedback reports are displayed in Table 61 and additional information on these measures is available at: *http://www.cms.gov/physicianfeedbackprogram/.*

TABLE 61—CLAIMS-BASED MEASURES FOR THE 2011 INDIVIDUAL PHYSICIAN FEEDBACK REPORTS

Measure No.	Measure title and description	NQF measure No. or measure steward *	Source of data
1	Acute Myocardial Infarction (AMI): Persistence of Beta-Blocker Treatment After a Heart Attack. 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.	0071	Administrative Claims.
2	Use of Spirometry Testing in the Assessment and Diagnosis of COPD) 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.	0577	Administrative Claims.
3	Antidepressant Medication Management: (a) Effective Acute Phase Treatment. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant drug during the entire 84-day Acute Treatment Phase. (b) Effective Continuation Phase Treatment. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant drug for at least 180 days.	0105	Administrative Claims.
4	Follow-Up After Hospitalization for Mental Illness 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. Two rates are reported: Rate 1: Percentage of patients who received follow-up within 30 days of discharge. Rate 2: Percentage of patients who received follow-up within 7 days of discharge.	0576	Administrative Claims.
5	Osteoporosis management in women 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.	0053	Administrative Claims.
6	Use of High-Risk Medications in the Elderly: (a) Patients Who Receive At Least One Drug To Be Avoided. Percentage of patients ages 65 years and older who received at least one high-risk medication in the measurement year. (b) Patients Who Receive At Least Two Different Drugs To Be Avoided.	0022	Administrative Claims.

TABLE 61—CLAIMS-BASED MEASURES FOR THE 2011 INDIVIDUAL PHYSICIAN FEEDBACK REPORTS—Continued

Measure No.	Measure title and description	NQF measure No. or measure steward *	Source of data
	Percentage of patients 65 years of age and older who received at least two different high-risk medications in the measurement year.		
7	Potentially Harmful Drug-Disease Interactions in the Elderly Percentage of Medicare patients 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. Report each of the three rates separately and as a total rate: Rate 1: A history of falls and a prescription for tricyclic antidepressants, antipsychotics or sleep agents. Rate 2: Dementia and a prescription for tricyclic antidepressants or anticholinergic agents. Rate 3: Chronic renal failure (CRF) and prescription for nonaspirin NSAIDs or Cox-2 Selective NSAIDs. Total rate: The sum of the three numerators divided by the sum of the three denominators.	National Committee for Quality Assurance (NCQA).	Administrative Claims.
8	International Normalized Ration (INR) for Beneficiaries Taking Warfarin and Interacting Anti-Infective Medications. 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.	0556	Administrative Claims.
9	Appropriate Follow-Up for Patients with HIV Percentage of patients diagnosed with HIV who received a CD4 count and an HIV RNA level laboratory test in the 6 months following diagnosis.	0568	Administrative Claims.
10	Ischemic Vascular Disease (IVD): Complete Lipid Profile 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.	0075	Administrative Claims.
11	Breast Cancer—Cancer Surveillance Percentage of female patients 18 and older with breast cancer who had breast cancer surveillance in the past 12 months.	0623	Administrative Claims.
12	Prostate Cancer—Cancer Surveillance Percentage of males with prostate cancer that have had their PSA monitored in the past 12 months.	0625	Administrative Claims.
13	Diabetes: Eye Exam 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 the measurement year.	0055	Administrative Claims.
14	Diabetes: Hemoglobin A1c Testing Percentage of adult patients with diabetes aged 18–75 years receiving one or more A1c test(s) per year.	0057	Administrative Claims.
15	Diabetes: Medical Attention for Nephropathy 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).	0062	Administrative Claims.
16	Diabetes: LDL–C Screening Percentage of adult patients with diabetes aged 18–75 who had an LDL–C test performed during the measurement year.	NCQA	Administrative Claims.
17	Pharmacotherapy Management of COPD Exacerbation 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. Two rates are reported: Rate 1: Dispensed a systemic corticosteroid within 14 days of the event. Rate 2: Dispensed a bronchodilator within 30 days of the event. Note: The eligible population for this measure is based on acute inpatient discharges and emergency department (ED) visits, not on patients; it is possible for the denominator to include multiple events for the same individual.	0549	Administrative Claims.

TABLE 61—CLAIMS-BASED MEASURES FOR THE 2011 INDIVIDUAL PHYSICIAN FEEDBACK REPORTS—Continued

Measure No.	Measure title and description	NQF measure No. or measure steward *	Source of data
18	Arthritis: Disease Modifying Antirheumatic Drug (DMARD) Therapy in Rheumatoid Arthritis. Percentage of patients 18 years and older, diagnosed with rheumatoid arthritis who have had at least one ambulatory prescription dispensed for a DMARD.	0054	Administrative Claims.
19	Coronary Artery Disease and Medication Possession Ratio for Statin Therapy. Medication Possession Ratio (MPR) for statin therapy for individuals over 18 years of age with coronary artery disease. Rate 1: Percentage of patients who are prescribed statin therapy in the measurement year. Rate 2: Average Medication Possession Ratio (MPR) of patients in the measurement year (MPR = the days supply of medication divided by the number of days in the measurement period). Rate 3: The percentage of patients with MPR ≥ 0.80 in the measurement year.	0543	Administrative Claims.
20	Therapeutic Monitoring: Annual Monitoring for Patients on Persistent Medications. 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. Report each of the four rates separately and as a total rate: Rate 1: Annual monitoring for patients on angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB). Rate 2: Annual monitoring for patients on digoxin. Rate 3: Annual monitoring for patients on diuretics. Rate 4: Annual monitoring for patients on anticonvulsants. Total Rate: The sum of the four numerators divided by the sum of the four denominators.	0021	Administrative Claims.
21	Deep Vein Thrombosis Anticoagulation At Least 3 Months 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.	0581	Administrative Claims.
22	Pulmonary Embolism Anticoagulation At Least 3 Months 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.	0593	Administrative Claims.
23	Monthly INR Monitoring for Beneficiaries on Warfarin 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.	0555	Administrative Claims.
24	Steroid Use—Osteoporosis Screening 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.	0614	Administrative Claims.
25	Appropriate Work-Up Prior To Endometrial Ablation Procedure 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.	0567	Administrative Claims.
26	Breast Cancer Screening Percentage of eligible women 40–69 who receive a mammogram in during the measurement year or in the year prior to the measurement year.	0031	Administrative Claims.
27	Hepatitis C: Viral Load Test 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.	0584	Administrative Claims.
28	Dyslipidemia New Medication 12-Week Lipid Test	0583	Administrative Claims.

TABLE 61—CLAIMS-BASED MEASURES FOR THE 2011 INDIVIDUAL PHYSICIAN FEEDBACK REPORTS—Continued

Measure No.	Measure title and description	NQF measure No. or measure steward *	Source of data
	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.		

* The NQF measure number is reported unless the measure is not NQF-endorsed, in which case the measure steward is reported.

The individual reports will not contain the average rate of preventable hospital admissions for the six ambulatory care-sensitive conditions identified above because these measures are not specified at the individual physician level at this time.

We again plan to display resource use measures that reflect average per capita cost for a given physician's Medicare patients. In addition to comparing average per capita costs of one physician's patients to the average per capita costs of his/her peers' patients, the reports will compare total per capita costs for patients with the following chronic conditions: Heart failure, chronic pulmonary obstructive disease (COPD), diabetes, and coronary artery disease.

b. Refinement of the Physician Feedback Program in 2011: Individual Physicians/Medical Group Practices/Specialties

As stated in the CY 2011 PFS proposed rule, deciding which physician(s) is/are responsible for the care of which beneficiaries is an important aspect of measurement (75 FR 40115). When attributing beneficiary cost information to physicians, we must balance between costs for delivered services that are within the physician's control and costs for delivered services that are not within their control. We recognize that attribution rules have the potential to alter incentives regarding how physicians coordinate and deliver care to beneficiaries and seek to encourage better care coordination and accountability for patient outcomes. In addition, determining how to make relevant comparisons of physicians to a standard or to their peers is also an important policy aspect of the Physician Feedback Program. In light of these issues, we are engaging in the efforts described below to help inform how to develop and produce this and future year's reports.

First, we are examining alternative attribution methods that would allow more Medicare beneficiaries to be matched to physicians for purposes of assessing the quality of care furnished and the associated resources. We plan to explore broader attribution models than we used in last year's Physician Feedback reports, in which beneficiaries were attributed to physicians/groups based on E/M services and a minimum cost threshold. Cost of service rules, for example, may better apply to physicians who commonly furnish surgical procedures or interventions, especially those that are high volume and/or high cost. We anticipate combining this effort with work to identify quality measures appropriate to the practices of these specialists. We recognize that characteristics of physicians and the scope of their medical practices vary far more than those of other provider types such as hospitals, home health agencies, and nursing homes and, thus, we want to ensure we develop sound attribution rules that recognize these variations and are appropriate for physicians.

We also are planning to investigate stratifying physicians by specialty and by the conditions they treat, which would allow both cost and clinical measures to reflect procedures and services that best portray physician practice patterns.

Second, we intend to examine whether to provide reports to groups of physicians who submit Medicare claims under a single tax identification number (TIN) to see if we can provide feedback reports that cover more physicians. TIN-level reporting may prove useful in situations where individual physicians have too few of some types of patients to allow for accurate reporting of cost measures or certain quality measures.

We seek comment on these and any other issues to ensure that the future Physician Feedback reports provide meaningful and actionable information.

c. Beyond 2011: Future Scale Up and Dissemination for Increased Physician Feedback Reporting

In CY 2012, we expect to expand dissemination of reports to cover 100,000 physicians nationally. In 2012, we expect to be able to evaluate whether leveraging the quality measures in the Physician Quality Reporting System will help achieve this goal. We recognize that our current inventory of quality measures, both claims-based and those used in the 2010 GPRO–1 quality measures, best covers primary care practitioners including family physicians, general practitioners, internists, geriatricians, and related medical non-procedural specialists. As the scope of measures, including outcomes, in the Physician Quality Reporting System increases and as more physicians report measures, we expect to be able to provide meaningful and actionable quality information to an increasing number of physicians. This increased participation will increase the breadth of Medicare physicians for whom Physician Feedback reports can be created.

Second, section 1848(n)(9)(A) of the Act, as added by section 3003 of the Affordable Care Act, requires the development, by not later than January 1, 2012, of a Medicare-specific episode grouper so that physicians can be compared on episode-based costs of care. The episode grouper will require further testing and refinement in order to see how well it integrates with other parameters, such as attribution and benchmarking, before it can be fully operational. The episode grouper is being developed to determine episode-based costs for a subset of selected high cost, high volume conditions for Medicare beneficiaries, including six of the following nine conditions: Hip fracture/hip replacement; pneumonia; heart attack; coronary artery disease; asthma; COPD; stroke; diabetes; and heart failure. Aspects of the episode grouper could be applied, on a limited basis, in Physician Feedback reports in 2012 or 2013, depending upon the testing and validation of the methodology. Section 1848(n)(9)(A)(iv) of the Act requires that the Secretary seek endorsement of the grouper by an entity with a contract under section 1890(a) of the Act. Plans to secure this endorsement are under development. We plan to make details of the Medicare grouper publicly available as required by section 1848(n)(9)(A)(iii)) of the Act.

In addition, we will continue to monitor developments regarding the National Quality Forum's project regarding resource use measures. Learning from this project is likely to help refine the next steps related to the scale up of the Physician Feedback reports.

Lastly, we will pursue how best to incorporate the production and dissemination of the feedback reports into the IT infrastructure of the agency. For example, in this year's reports we plan to use the Medicare Administrative Contractor to distribute the individual physician reports by e-mail. It is our intent in future years to use other mechanisms, such as a secure portal, for physicians to obtain and review their reports. It is critical for us to plan for the very significant, and ongoing, data and dissemination infrastructure that must be built for us to provide feedback reports to all physicians paid under the PFS.

As the science of quality measurement improves, attribution methodologies mature, participation rates in our reporting programs increase, and our IT infrastructure evolves, we will determine how best to incorporate these advances into a better physician feedback program. Furthermore, it is our intent to engage in continued dialogue with the physician community about ways to improve these reports and their dissemination.

4. The Value-Based Payment Modifier: Section 3007 of the Affordable Care Act

Section 1848(p) of the Act, as added by Section 3007 of the Affordable Care Act, requires the Secretary to ''establish a payment modifier that provides for differential payment to a physician or a group of physicians'' under the physician fee schedule ''based upon the quality of care furnished compared to cost * * * during a performance period.'' The provision requires that ''such payment modifier be separate from the geographic adjustment factors'' established for the physician fee schedule. We believe that this provision requires the Secretary to establish a differential payment under the physician fee schedule to reflect ''value,'' for example, the quality of care compared to cost, and that the value modifier is independent from the geographic adjustments applied under the fee schedule.

Section 1848(p)(4)(C) of the Act requires that the value modifier be implemented in a budget-neutral manner. Budget neutrality means that payments will increase for some physicians but decrease for others, 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 modifier. Over time, we expect that implementation of the value modifier will lead to more efficient use of services.

Section 1848(p)(4)(A) and (B) of the Act establish the time frame for implementation of the value modifier. Section 1848(p)(4)(B)(iii) of the Act requires the Secretary to apply the value 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 modifier with respect to all physicians and groups of physicians beginning not later than January 1, 2017.

Section 1848(p)(4) of the Act requires the Secretary to take a series of steps, beginning not later than January 1, 2012, and leading up to implementation of the value modifier on January 1, 2015. Section 1848(p)(4)(A) of the Act requires us to publish, not later than January 1, 2012, three items related to the establishment of the value modifier: (a) The quality of care and cost measures established by the Secretary for purposes of the modifier; (b) the dates for implementation of the value modifier; and (c) the initial performance period for application of value modifier in 2015.

Section 1848(p)(4)(B) of the Act requires the Secretary to begin implementing the value modifier through the physician fee schedule rulemaking process during 2013; this rulemaking would apply to value modifier payment adjustments for 2015. Section 1848(p)(4)(B) of the Act further requires the Secretary, to the extent practicable during the initial performance period, to provide information to physicians and physician groups about the quality of care furnished by the physician or group of physicians to Medicare beneficiaries compared to cost.

The value modifier is an important component in revamping how care and services are paid for under the physician fee schedule. Currently, payments under the physician fee schedule are generally based on the relative resources involved with furnishing each service, and adjusted for differences in resource inputs among geographic areas. Thus, all physicians in a geographic area are paid the same amount for individual services regardless of the quality of care or outcomes of services they furnish.

Although the fee schedule payments are or will soon be adjusted depending upon whether eligible professionals are satisfactory reporters of PQRS quality measures, successful electronic prescribers and meaningful users of electronic health records (EHRs),[7] these adjustments do not currently take into account performance on these quality measures. In addition, the fee schedule does not take into account the overall cost of services furnished or ordered by physicians for individual Medicare beneficiaries. These limitations mean that the physician fee schedule does not contain incentives for physicians to focus on: (1) The relative cost or value of each service they furnish or order; (2) the cumulative cost of their own services and the services that their beneficiaries receive from other providers; or (3) the quality and outcomes of all the care furnished to beneficiaries.[8]

We note that Medicare is beginning to implement value-based payment adjustments for other types of services. For example, recently, we published a final rule to implement the hospital value-based purchasing program that will affect hospitals beginning with FY 2013 discharges (76 FR 26490). In addition, section 3006 of the Affordable Care Act requires us to develop a plan to implement value-based purchasing programs for skilled nursing facilities, home health agencies, and ambulatory surgical centers. We view the physician value modifier as the companion value-based payment mechanism for physicians.

In implementing value-based purchasing initiatives generally, we seek to meet the following goals:

• Improving quality.

++ 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 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

[7] See, for example, section 1848(a)(8) of the Act, as added by section 3002(b) of the Affordable Care Act; section 1848(a)(7)(A) of the Act, as added by section Sec 4101 (b) of the HITECH Act.

[8] Source: MedPAC, Report to the Congress: Reforming the Delivery System, Chapter 1 (June 2008), available at: *http://www.medpac.gov/documents/Jun08_EntireReport.pdf.*

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, measures used by us 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.

• Lowering per-capita growth in expenditures.

++ Providers should be accountable for the cost of care, and be rewarded for reducing unnecessary expenditures and be responsible for excess expenditures.

++ In reducing excess expenditures, providers should continually improve the quality of care they deliver.

++ To the extent possible, and recognizing differences in payers' value based purchasing initiatives, providers should apply cost-reducing and quality-improving redesigned care processes to their entire patient population.

Our experience with providing physicians confidential feedback reports, which include various measures of cost and quality, is helping us to design and develop the value modifier. In addition, we seek to build upon best practices that have evolved in the private sector to provide meaningful and actionable information to physicians. For example, we recognize the importance of transparent methodologies and of procedural safeguards necessary to provide physicians with an opportunity to review the value modifier such as the one we will develop.[9]

We intend to move both deliberately and carefully because we recognize the complexities of calculating a reliable and valid measure of value that compares physicians against their peers and uses the measure to differentiate payment. We view this rulemaking as one part of an ongoing and extensive dialogue with health care stakeholders on how best to ensure development of a fair, meaningful, and actionable value modifier on which to differentiate payments to physicians.

a. Measures of Quality of Care and Costs

(1) Quality of Care Measures

Section 1848(p)(2) of the Act requires that the quality of care be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished. Section 1848(p)(2)(B) of the Act requires that the Secretary establish appropriate measures of the quality of care furnished by a physician or a group of physicians to Medicare beneficiaries such as measures that reflect health outcomes. The statute requires the measures to be risk adjusted as determined appropriate by the Secretary. Section 1848(p)(2)(B)(ii) of the Act requires the Secretary to seek endorsement of the quality of care measures by the entity with a contract under section 1890(a) of the Act, which is the National Quality Forum.

In establishing the quality of care measures for the value modifier, our interest is to move toward a core set of measures so that we can assess and benchmark physician performance. We are interested in ensuring that this set of core measures includes outcome measures, especially for care provided by specialists. We also want to start a discussion of potential measures that could provide a richer picture of the quality of care furnished by a physician. At our September 24, 2010, Listening Session on the Physician Feedback Program and Implementation of the Value-Based Payment Modifier for Fee-for-Service Medicare, the stakeholder community suggested the need for additional quality measures that focus on care coordination/care transitions, patient experience, and outcomes such as functional health status.[10] We agree with these suggestions and believe that these measures could provide a richer picture of the quality of care furnished by physicians to Medicare beneficiaries.

We view the requirement for the Secretary to establish, by January 1, 2012, the quality measures for the value modifier to be the first step in identifying a robust core set of measures of the quality of care furnished by physicians for use in the value modifier. We envision incorporating additional quality measures into the value modifier over time.

(A) Proposed Quality of Care Measures for the Value-Modifier

For purposes of section 1848(p)(4)(A)(i) of the Act, we propose to use performance on: (1) The measures in the core set of the Physician Quality Reporting System for 2012; (2) all measures in the GPRO of the Physician Quality Reporting System for 2012; and (3) the core measures, alternate core, and 38 additional measures in the Electronic Health Record Incentive Program measures for 2012. Table 62 lists these measures. We recognize that there are measures common to these two programs because they are derived from the proposed 2012 Physician Quality Reporting System and may be available for reporting in other CMS programs, such as the Medicare and Medicaid EHR Incentive Program as well as the Medicare Shared Savings Program. We note that measure titles, in some instances, may vary from program to program. Once these measures are finalized, we will identify the measures more fully to eliminate any duplication.

TABLE 62—PROPOSED QUALITY MEASURES FOR THE VALUE MODIFIER

Physician quality reporting system No.	Measure title	NQF Measure No.	Measure developer	EHR Incentive program	PQRS GPRO	PQRS Core
110	Preventative Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old.	0041	AMA–PCPI	X	X	
111	Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.	0043	NCQA	X	X	
112	Preventive Care and Screening: Screening Mammography.	0031	NCQA	X	X	

[9] See for example Ambulatory Quality Alliance, Performance Measurement Workgroup materials, available at: *http://www.ambulatoryqualityalliance.org/performancewg.htm;* New York Attorney General Settlement with Excellus, available at: *http://www.ag.ny.gov/bureaus/health_care/pdfs/Excellus%20Settlement.pdf.*

[10] Listening Session Regarding: Physician Feedback Program and Implementation of the Value-Based Payment Modifier for Fee-for-Service Medicare (Sept. 24, 2010) (see, for example, comments of Pacific Business Group on Health, Consumer Purchaser Disclosure Project), transcript available at: *https://www.cms.gov/PhysicianFeedbackProgram/Downloads/092410_Listening_Session_Feedback_Program_Transcript.pdf.*

TABLE 62—PROPOSED QUALITY MEASURES FOR THE VALUE MODIFIER—Continued

Physician quality reporting system No.	Measure title	NQF Measure No.	Measure developer	EHR Incentive program	PQRS GPRO	PQRS Core
113	Preventive Care and Screening: Colorectal Cancer Screening.	0034	NCQA	X	X	
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up.	0421	CMS–QIP	X		
TBD	Preventive Care: Cholesterol-LDL test performed.	N/A	CMS			X
TBD	Falls: Screening for Falls Risk	101	NCQA		X	
TBD	Cervical Cancer Screening	0032	NCQA	X		
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	0028	AMA–PCPI	X	X	X
235	Hypertension (HTN): Plan of Care	0017	AMA–PCPI		X	
236	Controlling High Blood Pressure	0018	NCQA	X	X	X
237	Hypertension (HTN): Blood Pressure Measurement.	0013	AMA–PCPI	X	X	
TBD	Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years.	N/A	CMS		X	X
6	Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.	0067	AMA–PCPI	X	X	
7	Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).	0070	AMA–PCPI	X	X	
118	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).	0066	AMA–PCPI		X	
TBD	Coronary Artery Disease (CAD): LDL <100 mg/dl.	NA	CMS		X	
197	Coronary Artery Disease (CAD): Lipid Control	0074	AMA–PCPI	X	X	
201	Ischemic Vascular Disease (IVD): Blood Pressure Management Control.	0073	NCQA	X	X	
204	Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.	0068	NCQA	X	X	X
TBD	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control < 100 mg/dl.	0075	NCQA	x	X	X
5	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0081	AMA–PCPI	X	X	
8	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	0083	AMA–PCPI	X	X	
228	Heart Failure: Left Ventricular Function (LVF) Testing.	N/A	CMS		X	
198	Heart Failure: Left Ventricular Function (LVF) Assessment.	0079	AMA–PCPI		X	
227	Heart Failure: Weight Measurement	0085	AMA–PCPI		X	
199	Heart Failure: Patient Education	0082	AMA–PCPI		X	
200	Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation.	0084	AMA–PCPI	X	X	
TBD	Monthly INR for Beneficiaries on Warfarin	555	CMS		X	
1	Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.	0059	AMA–PCPI	X	X	
TBD	Diabetes: Aspirin Use	0729	MN Community Measurement.		X	
3	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.	0061	NCQA	X	X	
TBD	Diabetes: Hemoglobin A 1 c Control (<8.0%)	575	NCQA	X	X	
2	Diabetes Mellitus: Low Density Lipoprotein (LDL–C) Control in Diabetes Mellitus.	0064	NCQA	X	X	X
117	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient.	0055	NCQA	X	X	
18	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.	0088	AMA–PCPI	X		
TBD	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care.	0089	AMA–PCPI	X		

TABLE 62—PROPOSED QUALITY MEASURES FOR THE VALUE MODIFIER—Continued

Physician quality reporting system No.	Measure title	NQF Measure No.	Measure developer	EHR Incentive program	PQRS GPRO	PQRS Core
119	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.	0062	NCQA	X	X	
163	Diabetes Mellitus: Foot Exam	0056	NCQA	X	X	
TBD	Diabetes Mellitus: Tobacco Non-Use	0729	MN Community Measurement.		X	
239	Weight Assessment and Counseling for Children and Adolescents.	0024	NCQA	X		
240	Childhood Immunization Status	0038	NCQA	X		
TBD	Appropriate Testing for Children with Pharyngitis	0002	NCQA	X		
TBD	Prenatal Care: Screening for Human Immunodeficiency Virus (HIV).	0012	AMA–PCPI	X		
TBD	Prenatal Care: Anti-D Immune Globulin	0014	AMA–PCPI	X		
53	Asthma Pharmacologic Therapy	0047	AMA–PCPI	X		
64	Asthma Assessment	0001	AMA–PCPI	X		
TBD	Use of Appropriate Medications for Asthma	0036	NCQA	X		
51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation.	0091	NCQA		X	
52	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.	0102	AMA–PCPI		X	
TBD	Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received.	N/A	CMS		X	
71	Oncology Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.	0387	AMA–PCPI	X		
72	Oncology Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients.	0385	AMA–PCPI	X		
102	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.	0389	AMA–PCPI	X		
9	Anti-depressant Medication Management: (a) Effective Acute Phase Treatment, (b) Effective Continuation Phase Treatment.	0105	NCQA	X		
TBD	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement.	0004	NCQA	X		
40	Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older.	0045	NCQA		X	
TBD	Low Back Pain: Use of Imaging Studies	0052	NCQA	X		
TBD	Chlamydia Screening for Women	0033	NCQA	X		
12	Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation.	0086	AMA–PCPI	X		
46	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.	0097	AMA–PCPI		X	
TBD	30-Day Post Discharge Physician Visit	N/A	Colorado Foundation for Medical Care.		X	

We seek comment on whether to include additional measures from the Physician Quality Reporting System (which are described elsewhere in this proposed rule) in the measures that we propose for the value modifier. We also seek comment on whether there are any measures included here that should be excluded from the value modifier, and on the appropriate number of measures for inclusion.

To the extent that the 2013 measures adopted for the Physician Quality Reporting System and Electronic Health Record Incentive Program are different than those used in 2012, we would consider, through rulemaking next year, revising the value modifier quality measures applicable to 2013 to be consistent with the revisions made to the measures for those programs. Indeed, Section 1848(p)(9) of the Act directs us to coordinate the value modifier quality measures with the Physician Feedback Program, and, as the Secretary determines appropriate, other similar provisions of Title XVIII of the Social Security Act. We plan to coordinate the value modifier with the Physician Feedback Program, the Physician Quality Reporting System, and the EHR incentive program. We seek comment on the proposed measures and on our interest to establish a core measure set for the value modifier.

(B) Potential Quality of Care Measures for Additional Dimensions of Care in the Value Modifier

As described previously, one of our goals is to start a discussion about potential measures that could provide a richer picture of the quality of care furnished by a physician. For example, we are very interested in quality measures that assess the care provided by specialists. We specifically seek

comment from specialists about measures that are not included in the list of proposed measures.

We also seek comment on the types of measures identified below as well as the 28 administrative claims measures (described above with respect to the 2011 Physician Feedback reports) and whether we should include them in the value modifier. We especially urge the physician community and private payers that have been engaged in pay-for-performance programs to identify other quality measures that they have used and to describe their experience with these measures. We seek comment on how the measures discussed below align with current private sector quality measurement initiatives. To the extent that such measures are not currently developed, we would use the established agency procedures to develop such measures.

(i) Outcome Measures

We are very interested in moving toward a core quality of care measure set for the value modifier that includes outcome measures. For example, the Physician Feedback reports already display the rate of potentially preventable hospital admissions for six ambulatory care sensitive conditions at the practice group level: Diabetes, bacterial pneumonia, dehydration, chronic obstructive pulmonary disease (COPD), urinary tract infection, and congestive heart failure. These measures have been developed by the Agency for Healthcare Research and Quality and specifications for these measures can be found at *http://www.qualityindicators.ahrq.gov/modules/PQI_TechSpec.aspx.* We also are developing an all-cause hospital readmission measure for potential use in the Shared Savings Program, and section 1886(q)(8) of the Act requires us to develop an all-patient hospital readmission measure. We are considering use of these measures for physicians and physician groups. Our goal is to focus on outcomes of care for which it would be appropriate to assess physician performance. We seek comments about these potential measures for physicians. Although we are not proposing these measures at this time, we are soliciting comment and will consider including these outcome measures in the value modifier.

We also specifically seek suggestions about other outcome measures that would be appropriate measures of the quality of care furnished for purposes of the value modifier. For example, section 931 of the Public Health Service Act, as added by section 3013(a) and amended by section 10303 of the Affordable Care Act, also requires the Secretary to develop and periodically update provider-level outcome measures for physicians, among other types of providers. We also could consider development of measures that examine emergency room use for ambulatory care sensitive conditions. We are interested in outcome measures that can be calculated from existing Medicare claims data and do not require reporting by physicians. In addition, we are particularly interested in comments on potential measures of complications that would be appropriate to include in the value modifier.

(ii) Care Coordination/Transition Measures

We believe that care transitions such as transition of a beneficiary from an inpatient setting to the community or to a post-acute setting are important aspects of quality of care furnished. Successful transitions help ensure that a beneficiary is on a path to improvement and could avoid readmission. We believe that several aspects of the care transition could be developed into quality of care measures for purposes of the value modifier. For example, we could potentially consider developing a measure that would assess whether an appointment was set up or whether the hospitalized beneficiary saw a physician during a specified post-discharge period. This measure could apply to both the hospital physician and the community physician. In addition, beneficiaries often have unscheduled admissions (such as, via an emergency room) of which their primary physician is not made aware. We are considering including a care transition/care coordination measure that would involve a hospital physician checking to see if the hospital has notified the beneficiary's primary physician of an unscheduled admission (if the hospital and community physician were not the same).

Another aspect of care coordination could involve services that are ordered by one physician but furnished by another physician. Under this scenario, the treating physician may send a report back to the ordering physician. However, this is not always the case. The lack of coordination between two physicians involved in the beneficiary's care could be a missed opportunity to provide optimal, seamless care for the beneficiary. A care coordination measure could potentially assess the extent to which the report is sent back to the ordering physician and whether the furnishing physician has confirmation that the report was actually received.

We seek input about these and other potential aspects of care coordination/transitions for which measures could be developed and/or used for purposes of the value modifier. To the extent commenters are aware of potential measures that address care coordination/transitions that we could use, we welcome such suggestions. We would propose the specific measures through notice and comment rulemaking before including them as measures of the quality of care furnished for purposes of the value modifier.

(iii) Patient Safety, Patient Experience and Functional Status:

We believe that it is important to develop measures of patient safety, patient experience and functional status for purposes of the value modifier. A potential patient safety measure might involve use of a surgical checklist. We seek comment about such a measure and other potential patient safety measures that could be developed and/or used for purposes of the value modifier. To the extent commenters are aware of potential measures of patient safety, patient experience, or functional status that we could use, we welcome such suggestions. We would propose the specific measures through notice and comment rulemaking before including them as measures of the quality of care furnished for purposes of the value modifier.

(2) Cost Measures

Section 1848(p)(3) of the Act requires that cost measures used in the value modifier be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary. This composite would eliminate the effect of geographic adjustments in payment rates and account for risk factors and other factors determined appropriate by the Secretary. In our Physician Feedback reports, we currently use a total per capita cost measure and per capita cost measures for the overall costs for beneficiaries with four chronic conditions: Chronic obstructive pulmonary disease; heart failure; coronary artery disease; and diabetes. These per capita cost measures are price standardized and risk adjusted to ensure geographic and clinical comparability, as required by section 1848(p)(3) of the Act. These measures are described in more detail in the Detailed Methodology Specification document accompanying the 2010 Physician Feedback reports.[11]

[11] The Detailed Methodology Specifications are available at: *https://www.cms.gov/PhysicianFeedbackProgram/Downloads/2010_QRUR_ Detailed_Methodology.pdf.*

(A) Proposed Cost Measures for the Value Modifier

For purposes of section 1848(p)(4)(A)(i) of the Act, we propose to use total per capita cost measures and per capita cost measures for beneficiaries with these four chronic conditions (chronic obstructive pulmonary disease; heart failure; coronary artery disease; and diabetes) in the value modifier. These cost measures would be compared to the quality of care furnished for use in determining the value modifier. We seek comment on this proposal.

(B) Potential Cost Measures for Future Use in the Value Modifier

During 2012 we will test and plan how to use an ''episode grouper.'' The purpose of the episode grouper is to combine separate, but clinically related items and services into an episode of care for a beneficiary. Section 1848(n)(9)(A) of the Act requires us to develop an episode grouper so that physicians can be compared on episode-based costs of care. In order to comply with this statutory requirement, we have awarded separate contracts to four different project teams. We have tasked each project team to design a ''prototype'' of the episode grouper by determining episode-based costs for selected high-cost, high-volume conditions that occur among Medicare beneficiaries, including six of the following nine conditions: Hip fracture/hip replacement; pneumonia; heart attack; coronary artery disease; asthma; COPD; stroke; diabetes; and heart failure. By January 1, 2012, we will select one project team's prototype. The selected team will then be tasked to develop episode groupers for a more comprehensive set of conditions over a four-year period.

As a transition to implementing the episode grouper, we could use cost measures based on the inpatient hospital Medicare Severity Diagnosis Related Groups (MS–DRG) classification system. Specifically, we could use allowed Parts A and B charges per beneficiary for all services furnished on the day of admission and furnished through a specific number of days after the day of discharge. We are currently assessing how to attribute episode costs to physicians. We seek comment on whether we should pursue the MS–DRG approach in the near term while we develop episode-based cost measures for a significant number of high-cost and high-volume conditions in the Medicare program.

In addition, we specifically seek comment on the resource and cost measures used in private sector initiatives and how they are used to profile physicians compared to the quality of care provided.

b. Assessing Physician Performance and Applying the Value Modifier

Apart from the measures that would be used for purposes of applying the value modifier, there are a number of issues related to the implementation of the value modifier including steps for both measurement of performance and application of payment adjustments. While we are not making proposals on these issues at this time, we have briefly described them below and welcome public comments to be considered as we develop proposals on the value modifier for future rulemaking.

Pursuant to statutory requirements, we are examining how to create composites of measures of quality of care and of cost from the measures we have proposed so that we can compare quality relative to cost. We are also examining how to make appropriate risk and other adjustments to these measures. In addition, we are examining how to attribute beneficiaries to physicians to develop meaningful and actionable physician profiles for use in the value modifier. Some of the issues involved with examining attribution rules were discussed earlier in the discussion of Physician Feedback reports and include issues of sample size. We are also developing appropriate peer groups or benchmarks in order to compare physicians on the value modifier.

As previously mentioned, prior to application of the value modifier to all physicians and physician groups in 2017, section 1848(p)(4)(B)(iii) of the Act allows the Secretary in 2015 and 2016 to apply the value modifier to specific physicians and physician groups the Secretary determines appropriate. For example, we could apply the value modifier to physicians who are outliers (as identified individually, by practice group, or by geographic region) compared to national or regional areas in terms of high cost and low quality. Alternatively, we could apply the modifier to physicians who treat the conditions that are most prevalent and/or most costly, among Medicare beneficiaries.

As stated previously, we seek comment on these issues and other issues related to implementation of the value modifier. Our plan is to begin implementing the value modifier through the rulemaking process during 2013 as required by section 1848(p)(4)(B)(i) of the Act. We seek input from stakeholders as we work on these issues.

c. Dates for Implementation of the Value Modifier

Section 1848(p)(4)(B)(iii) of the Act requires that the Secretary apply the value modifier for items and services furnished beginning on January 1, 2015, with respect to specific physicians and groups of physicians, and not later than January 1, 2017, with respect to all physicians and groups of physicians. As required by section 1848(p)(4)(B)(i) of the Act, we will begin implementation of the value modifier through the rulemaking process during 2013 for the physician fee schedule effective for CY 2014. We anticipate that the methodology we propose to calculate the value modifier may be further refined, if necessary, during the 2014 rulemaking process for the physician fee schedule that will take effect in 2015.

d. Initial Performance Period

Section 1848(p)(4)(B)(ii)(I) of the Act requires the Secretary to specify an initial performance period for the application of the value modifier with respect to 2015. We propose that the initial performance period be the full calendar year 2013, that is, January 1, 2013 through December 31, 2013. The value modifier that is applied to items and services furnished by specific physicians and groups of physicians under the 2015 physician fee schedule would be based on performance during 2013. We propose this performance period because some claims for 2013 (which could be used in cost or quality measures) may not be fully processed until 2014. As such, we will need adequate lead time to collect performance data, assess performance, and construct and compute the value modifier during 2014 so that it can be applied to specific physicians starting January 1, 2015, as required by statute. As we have done in other payment systems, we plan to use claims that are paid within a specified time period, such as, 90-days after 2013, for assessment of performance and application of the value modifier for 2015. We will propose the specific cut-off period as part of the more detailed methodology for computation and application of the value modifier in future rulemakings. We seek comment on this proposed performance period.

e. Other Issues

We also seek comment on a number of issues related to the development of the value modifier, which we will address in future rulemaking. Although we are not proposing particular policies

at this time, we seek comment on two specific issues.

(1) Systems-Based Care

Section 1848(p)(5) of the Act requires the Secretary, as appropriate, to apply the value-based modifier in a manner that promotes systems-based care. We seek comment on how we might determine the scope of systems-based care and how best to promote it in applying the value modifier. For example, systems-based care might include an integrated group practice participation in the Shared Savings Program, a medical home, or an Innovation Center program that promotes systems-based care. We also could implement an attribution method that attributes patients to a collection of physicians that treat patients in common to encourage better coordination of care. Additionally, we could promote systems-based care by developing a common set of quality measures on which all providers would be evaluated. We seek comment on these and other ways in which we could promote systems-based care through the application of the value modifier.

(2) Special Circumstances for Physicians in Rural Areas and Other Underserved Communities

Section 1848(p)(6) of the Act requires the Secretary in applying the value modifier, as appropriate, to take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities. We seek comment on how we should identify physicians or groups of physicians in rural areas and other underserved communities, the specific special circumstances they face, and once identified, how these special circumstances should be taken into account for purposes of applying the value modifier. In addition, we seek comment on the organizational structures and practices that rural physicians and other underserved communities use and how we could apply a value modifier in these areas to accommodate their special circumstances.

J. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window Policy and the Impact on Wholly Owned or Wholly Operated Physician Practices

1. Introduction

On June 25, 2010, the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (PACMBPRA) (Pub. L. 111–192) was enacted. Section 102 of this Act entitled, ''Clarification of 3-Day Payment Window,'' clarified when certain services furnished to Medicare beneficiaries in the 3-days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1-day) preceding an inpatient admission should be considered ''operating costs of inpatient hospital services'' and therefore included in the hospital's payment under the Hospital Inpatient Prospective Payment System (IPPS). This policy is generally known as the ''3-day payment window.'' Under the 3-day payment window, a hospital (or an entity that is wholly owned or wholly operated by the hospital) must include on the claim for a Medicare beneficiary's inpatient stay, the technical portion of any outpatient diagnostic services and admission-related nondiagnostic services provided during the payment window. The new law makes the policy pertaining to admission-related nondiagnostic services more consistent with common hospital billing practices. Section 102 of the PACMBPRA is effective for services furnished on or after June 25, 2010.

2. Background

We discussed changes to the 3-day payment window in the interim final rule with comment period that was issued as part of last year's IPPS final rule (75 FR 50346). The law makes no changes to the billing of ''diagnostic services'' furnished during the 3-day payment window, which are included in the ''operating costs of inpatient hospital services'' pursuant to section 1886(a)(4) of the Act. All diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or wholly operated by the hospital), on the date of a beneficiary's admission or during the 3-days (1-day for a non-subsection (d) hospital) immediately preceding the date of a beneficiary's inpatient hospital admission, continue to be included on the Part A bill for the beneficiary's inpatient stay at the hospital. In accordance with section 102(a)(1) of the PACMBPRA, for outpatient services furnished on or after June 25, 2010, all nondiagnostic services, other than ambulance and maintenance renal dialysis services, provided by the hospital (or an entity wholly owned or wholly operated by the hospital) on the date of a beneficiary's inpatient admission and during the 3 calendar days (1 calendar day for a nonsubsection (d) hospital) immediately preceding the date of admission are deemed related to the admission and, therefore, must be billed with the inpatient stay, unless the hospital attests that certain nondiagnostic services are unrelated to the hospital claim (that is, the preadmission nondiagnostic services are clinically distinct or independent from the reason for the beneficiary's inpatient admission). In such cases, the unrelated outpatient hospital nondiagnostic services are covered by Medicare Part B, and the hospital may separately bill for those services.

Prior to the enactment of section 102 of the PACMBPRA clarifying the 3-Day Payment Window, the term ''related to the admission'' was defined in section 40.3, Chapter 3, Inpatient Hospital Billing, of the Medicare Claims Processing Manual (Pub. 100–04) to mean an exact match between the principal ICD–9 CM diagnosis codes for the outpatient encounter and the inpatient admission. On November 5, 1990, section 4003(a) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) amended the statutory definition of ''operating cost of inpatient hospital services'' to include the costs of certain services furnished prior to admission. Section 4003(a) also required that these preadmission services be included on the Medicare Part A bill for the subsequent inpatient stay. With this amendment, section 1886(a)(4) of the Act defines the operating costs of inpatient hospital services to include diagnostic services (including clinical diagnostic laboratory tests) or other services related to the admission (as defined by the Secretary) furnished by the hospital (or by an entity that is wholly owned or wholly operated by the hospital) to the patient during the 3-days prior to the date of the patient's admission to the hospital.

Section 1886(a)(4) of the Act was further amended by section 110 of the Social Security Amendments of 1994 (Pub. L. 103–432) enacted on October 31, 1994. This provision revised the payment window for hospitals that are excluded from the IPPS to include only those services furnished by the hospital or an entity wholly owned or wholly operated by the hospital during the 1-day (instead of the previous 3-days) prior to the patient's hospital inpatient admission. The hospital and hospital units excluded from the IPPS and affected by this policy are psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals. In the FY 1996 IPPS final rule (60 FR 45840), we noted that the term ''day'' refers to the entire calendar-day immediately preceding the date of admission and not the 24-hour time period that immediately precedes the hour of admission.

On February 11, 1998, we published a final rule (63 FR 6864), that responded to public comments received on a prior interim final rule on this policy. In that final rule, we confirmed that ambulance services and chronic maintenance of renal dialysis services are excluded from the 3-day payment window. This final rule also clarified that the payment window applies to outpatient services that are otherwise billable under Part B and does not apply to nonhospital services that are generally covered under Part A (such as home health, skilled nursing facility, and hospice). In addition, the rule clarified the terms ''wholly owned or operated'' and ''admission-related'' for nondiagnostic services.

The 1998 final rule (63 FR 6866) defined an entity as wholly owned or wholly operated if a hospital has direct ownership or control over another entity's operations. Specifically, 42 CFR 412.2(c)(5)(i) states, ''An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.'' The 1998 final rule also stated ''that we have defined services as being related to the admission only when there is an exact match between the ICD–9–CM diagnosis code assigned for both the preadmission services and the inpatient stay.'' The rule also stated ''A hospital-owned or hospital-operated physician clinic or practice is subject to the payment window provision.'' Therefore, related preadmission nondiagnostic services provided by a wholly owned or wholly operated physician clinic or practice are also included in the 3-Day (or 1-day) payment window policy, and services were considered related when there was an exact match between ICD–9 CM diagnosis codes for the outpatient encounter and the inpatient admission.

Prior to the June 25, 2010 enactment of section 102(a)(1) of PACMBPRA (Pub. L. 111–192), the payment window policy for preadmission nondiagnostic services was rarely applied in the wholly-owned or operated physician's office or clinic because, as noted, the policy required an exact match between the principal ICD–9 CM diagnosis codes for the outpatient services and the inpatient admission. Because of the exact match policy, very few services furnished in a physician's office or clinic that is wholly owned or operated by the hospital would be subject to the policy. Because the policy applied only in such narrow circumstances, until the recent statutory change, we have not provided further guidance to wholly owned or wholly operated physician offices on how nondiagnostic services are to be included on hospital bills when the 3-day payment window applied. However, the statutory change to the payment window policy made by Public Law 111–192 significantly broadened the definition of nondiagnostic services that are subject to the payment window to include any nondiagnostic service that is clinically related to the reason for a patient's inpatient admission, regardless of whether the inpatient and outpatient diagnoses are the same.

The FY 2012 IPPS proposed rule (76 FR 25960) further discusses application of the 3-day payment window for both preadmission diagnostic and related nondiagnostic services furnished to a patient at wholly owned or wholly operated physician practices after June 25, 2010. We do not know how many physician offices will meet this definition of wholly owned or wholly operated. Our expectation is that most hospital-owned entities providing outpatient services would be considered part of the hospital, likely as an outpatient department, and not separate physician clinics or practices. However, we believe there may be at least some hospital-owned clinics that meet the definition of a wholly owned or wholly operated physician practice. When a physician furnishes a service in a hospital, including an outpatient department of a hospital, Medicare pays the physician under the physician fee schedule, generally at a facility-based payment rate that is lower than the ''nonfacility'' payment rate in order to avoid duplication of payment for supplies, equipment, and staff that are paid directly to the hospital by Medicare.

3. Applicability of the 3-Day Payment Window Policy for Services Furnished in Physician Practices

In circumstances where the 3-day payment window applies to nondiagnostic services related to an inpatient admission furnished in a wholly owned or wholly operated physician practice, we propose that Medicare would make payment under the physician fee schedule for the physicians' services that are subject to the 3-day payment window at the facility rate. As explained more fully later in this section, the services that are subject to the 3-day payment window would be billed to Medicare similar to services that are furnished in a hospital, including an outpatient department of a hospital. On or after January 1, 2012, we propose that when a physician furnishes services to a beneficiary in a hospital's wholly owned or wholly operated physician practice and the beneficiary is admitted as an inpatient within 3 days (or, in the case of non-IPPS hospitals, 1 day), the payment window will apply to all diagnostic services furnished and to any nondiagnostic services that are clinically related to the reason for the patient's inpatient admission regardless of whether the reported inpatient and outpatient ICD–9–CM diagnosis codes are the same.

a. Payment Methodology

Specifically, we would establish a new Medicare HCPCS modifier that will signal claims processing systems to provide payment at the facility rate. We propose to pay only the Professional Component (PC) for CPT/HCPCS codes with a Technical Component (TC)/PC split that are provided in the 3-day (or, in the case of non-IPPS hospitals, 1-day) payment window in a hospital's wholly owned or wholly operated physician practice. We propose to pay the facility rate for codes without a TC/PC split to avoid duplicate payment for the technical resources required to provide the services as those costs will be included on the hospital's inpatient claim for the related inpatient admission. The facility rate includes physician work, malpractice, and the facility practice expense, which is a payment to support services provided by the physician office when a physician treats patients at another facility, such as updating medical records. We propose to modify our regulation at § 414.22(b)(5)(i), which defines the sites of service that result in a facility practice expense RVU for payment, to add an entity that is wholly owned or wholly operated by a hospital, as defined in § 412.2(c)(5)(ii) when that entity furnishes preadmission services.

If this proposal is finalized, we would establish a new HCPCS modifier through sub-regulatory guidance. We would require that this modifier be appended to the physician preadmission diagnostic and admission-related nondiagnostic services, reported with HCPCS codes, which are subject to the 3-day payment window policy. Each wholly owned or wholly operated physician's practice would need to manage its billing processes to ensure that it billed for its physician services appropriately when a related inpatient admission has occurred. The hospital would be responsible for notifying the practice of related inpatient admissions for a patient who received services in a wholly owned or wholly operated

physician practice within the 3-day (or when appropriate 1-day) payment window prior to the inpatient stay. We would make the new modifier effective for claims with dates of service on or after January 1, 2012, and wholly owned or wholly operated physician practices would receive payment at the facility rate for related nondiagnostic services and receive payment for only the professional component for diagnostic services effective for services furnished on or after January 1, 2012.

We realize that the time frames associated with the global surgical package for many surgical services could overlap with the 3-day (or 1-day) payment window policy. Global surgical payment rules apply to major and minor surgeries, and endoscopies. Section 40.1 of the Claims Processing Manual (100–04 chapter 12 Physician/Nonphysician Practitioners) defines the global surgical package. Procedures can have a global surgical period of 0, 10, or 90-days. Generally, the global period for major surgeries is 1-day prior to the surgical procedure and 90-days immediately following the procedure. For minor surgeries, the global period is the-day of the procedure and 10-days immediately following the procedure.

Medicare payment for the global surgical package is based on the typical case for a procedure, and includes preoperative visits, intra-operative services, and complications following surgery, postoperative visits, postsurgical pain management, supplies, and miscellaneous other services such as dressing changes and removal of sutures or staples. Medicare makes a single payment to the treating physician (or group practice) for the surgical procedure and any of the pre- and postoperative services typically associated with the surgical procedure provided within the global surgical period (10 or 90-days). The same section of the Claims Processing Manual (100–04 chapter 12 Physician/Nonphysician Practitioners) also discusses the services that are not included in payment for the global surgical period. In general, these services are unrelated to the surgery, are diagnostic or are part of the decision to pursue surgery, or are related to the surgery but are so significant they warrant an additional payment. Some examples of services not included in payment for the global surgical period include the initial evaluation of the problem by the surgeon to determine the need for major surgery; services of another physician; visits unrelated to the diagnosis for the surgical procedure unless the visits occur due to surgical complications; treatment that is not part of the normal recovery from surgery; diagnostic tests; distinct surgical procedures that are not re-operations; treatment for postoperative complications that require a return trip to the operating room; critical care unrelated to the surgery where a seriously injured or burned patient is critically ill and requires the constant attention of the physician; and immunosuppressive therapy for organ transplants.

The time frames for application of the 3-day payment window and the global surgical package could overlap. In some cases, the application of the 3-day payment window is straightforward. For example, a patient could have minor surgery in a wholly owned or wholly operated physician's office and, due to complications, need to be admitted within 3-days to an acute care hospital paid under the IPPS for follow-up surgery. Under the 3-day payment window policy, the practice expense portion of the initial surgery and any pre- and postoperative visits associated with the surgery (both those subject to the global surgery rules and separate diagnostic procedures) should be included on the hospital's Part A claim for the inpatient admission. The wholly owned or wholly operated physician practice would bill for the surgery performed for the inpatient as well as for the initial surgical procedure performed in the physician practice that started the global period. The wholly owned or wholly operated physician practice would apply the HCPCS modifier that CMS would pursue to implement the 3-day payment window to each of these services HCPCS code. Medicare would pay the physician practice for the initial surgical procedure and the related procedure following inpatient admission at the facility rate. Finally, any preadmission diagnostic tests conducted by the wholly owned or wholly operated physician practice in the 3-day payment window would be included on the physician practice's claim with the anticipated HCPCS modifier, and Medicare would pay the wholly owned or wholly operated physician practice only the professional portion of the service.

However, the situation could arise where a global surgical period overlaps with the 3-day payment window, but the actual surgical procedure with the global surgical package occurred before the 3-day payment window. In this case, several post-operative services, such as follow-up visits, would occur during the global period, but the surgeon would not bill separately for those services. We propose that services with a global surgical package would be subject to the 3-day payment window policy when wholly owned or wholly operated physician practices furnish preadmission diagnostic and nondiagnostic services that are clinically related to an inpatient admission when the date of the actual surgical procedure falls within the 3-day payment window policy. However, when the actual surgical procedure for a service that has a global surgical package is furnished on a date that falls outside the 3-day payment window, the 3-day window policy would not apply. We do not believe it would be appropriate to require the wholly owned or wholly operated physician practice to unbundle the post operative services associated with the global surgical procedure so that the practice expense portion of those services could be paid under the PFS at the facility rate and the costs included on the hospital's inpatient claim. However, any service that a wholly owned or wholly operated physician practice would bill separately from the global surgical package, such as a separate initial evaluation of a problem by the surgeon to determine the need for surgery or separate diagnostic tests, would continue to be subject to the 3-day payment window policy.

b. Identification of Wholly Owned or Wholly Operated Physician Practices

The 1998 final rule (63 FR 6864) defined wholly owned or wholly operated as a hospital's direct ownership or control over another entity's operations. In that rule, we added the regulation at 42 CFR 412.2(c)(5)(i) which states, ''An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.'' Physician practices self-designate whether they are owned or operated by a hospital during the Medicare enrollment process. Currently, a physician practice enrolls in Medicare with CMS form ''855B.'' This enrollment form reports pertinent practice information such as ownership, organizational structure, and operational duties. Likewise, hospitals enroll in Medicare using CMS form ''855A'' also reporting pertinent hospital information such as ownership, organizational structure and operational duties. Medicare Administrative Contractors update files of physician practices that are owned and operated by hospitals, and the files of hospitals that own those physician practices, in

their claims processing systems and use that data to confirm an ownership relationship for identified physician practices. We will investigate the feasibility of establishing national system edits within the Common Working File to fully identify whether a physician practice is wholly owned or wholly operated by a hospital and to associate such practice with its affiliated hospital.

K. Hospital Discharge Care Coordination

We are committed to achieving better care for individuals, better health for populations, and reduced expenditure growth. Reforms such as Accountable Care Organizations and Medical Homes work to achieve these goals. We are also committed to reforms to the fee-for-service payment system to achieve these goals. We recently launched the Partnership for Patients, (in April 2011), a national patient safety initiative that includes the Community Based Care Transitions Program, which provides funding to community-based organizations to coordinate a continuum of post-acute care in order to test models for improving care transitions for high risk Medicare beneficiaries.

Care coordination involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to the beneficiary's primary physician in the community could 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 coordination and care transitions could improve the quality of care while simultaneously decreasing costs. We are interested in 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.

Care coordination is a component of many evaluation and management (E/M) services. Under the physician fee schedule, there are two hospital discharge codes, hospital discharge day management services CPT codes 99238 (Hospital discharge day management; 30 minutes or less) and 99239 (Hospital discharge day management; more than 30 minutes). Both of these codes include care coordination activities. The specific physician activities for care coordination associated with the hospital discharge day management codes as shown in Table 63 include the following:

- Providing care coordination for the transition including instructions for aftercare to caregivers.
- Ordering and arranging for post discharge follow-up professional services and testing.
- Discussing aftercare treatment with the beneficiary, family, and other healthcare professionals.
- Informing the primary care or referring physician of discharge plans.
- Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this hospitalization.
- Revise treatment plan(s) and communicate with beneficiary and/or caregiver, as necessary.

Providing necessary care coordination also is a component of the office visit CPT codes 99203 (Level 3 new patient office or other outpatient visit) and 99213 (Level 3 established patient office or other outpatient visit) that a beneficiary's primary physician would use to bill for the first visit after discharge. The physician activities for care coordination associated with these E/M services as shown in Table 63 include providing necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this office visit.

The clinical vignettes that are used to value the resources included in these codes are shown in Table 63. We have provided the full clinical vignettes used by the American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC) to develop recommended RVU values for the resources included in the discharge day management and E/M codes. These vignettes detail all the specific physician activities that the AMA RUC considered for these CPT codes, including hospital discharge care coordination activities.

TABLE 63—AMA RUC CLINICAL VIGNETTE

CPT code	Long descriptor	Vignette	Pre service	Intra service	Post service
99238	Hospital discharge day management; 30 minutes or less.	Discharge visit for a 55-year-old male admitted with a community-acquired pneumonia is seen in preparation for discharge from the hospital. He is euvolemic, afebrile, asymptomatic, and his oxygen saturations are normal.	• Review data not available on the unit (such as diagnostic and imaging studies). • Communicate with other professionals and with patient or patient's family.	• Review medical records and data available on the unit. • Obtain an interval history • Perform a physical exam. • Consider relevant data, options, and risks and formulate/revise diagnosis and treatment plan(s) including making the decision for discharge. • 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. • Reconcile medications with attention to pre-admission therapy, inpatient therapy and outpatient formulary and write prescriptions. • Complete discharge and aftercare forms. • Inform the primary care or referring physician of discharge plans. • Complete medical record documentation.	• Complete discharge records. • Handle (with the help of clinical staff) any treatment failures or adverse reactions to medications that may occur after discharge. • Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this hospitalization. • Receive and respond to any interval testing results or correspondence, including obtaining any results pending at discharge. • Revise treatment plan(s) and communicate with patient and/or caregiver, as necessary.
99239	Hospital discharge day management; more than 30 minutes.	Discharge visit for a 75-year-old female who required a below-the knee amputation for an infected non-healing ulcer on her right foot is seen in preparation for discharge from the hospital. She has Type 2 diabetes mellitus, ischemic cardiomyopathy, atherosclerotic peripheral vascular disease, hypertension, chronic renal insufficiency, and dementia. She is no longer delirious, her blood sugars are well controlled, and she is at her baseline weight. She is being discharged back to the nursing home.	• Review data not available on the unit (such as diagnostic and imaging studies). • Communicate with other professionals and with patient or patient's family.	• Review medical records and data available on the unit. • Obtain an interval history. • Perform a physical exam. • Consider relevant data, options, and risks and formulate/revise diagnosis and treatment plan(s) including making the decision for discharge. • 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. • Reconcile medications with attention to pre-admission therapy, inpatient therapy and outpatient formulary and write prescriptions. • Complete discharge and aftercare forms. • Inform the primary care or referring physician of discharge plans. • Complete medical record documentation.	• Complete discharge records. • Handle (with the help of clinical staff) any treatment failures or adverse reactions to medications that may occur after discharge. • Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this hospitalization. • Receive and respond to any interval testing results or correspondence, including obtaining any results pending at discharge. • Revise treatment plan(s) and communicate with patient and/or caregiver, as necessary.

TABLE 63—AMA RUC CLINICAL VIGNETTE—Continued

CPT code	Long descriptor	Vignette	Pre service	Intra service	Post service
99203	Office/outpatient visit, new ..	Initial office visit for a 63-year-old female with hypertension presents for a pre-employment physical after moving to the area. Her blood pressure has been adequately controlled with her current medication on home blood pressure monitoring.	• Review the medical history form completed by the patient and vital signs obtained by clinical staff. • Communicate with other health professionals.	• Obtain a detailed history. • Perform a detailed examination. • Consider relevant data, options, and risks and formulate a diagnosis and develop a treatment plan (low complexity medical decision making). • Discuss diagnosis and treatment options with the patient. • Address the preventive health care needs of the patient. • Reconcile medication(s) • Write prescription(s). • Order and arrange diagnostic testing or referral as necessary.	• Complete the medical record documentation. • Handle (with the help of clinical staff) any treatment failures or adverse reactions to medications that may occur after the visit. • Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this office visit. • Receive and respond to any interval testing results or correspondence. • Revise treatment plan(s) and communicate with patient, as necessary.
99213	Office/outpatient visit, est	Office visit, established patient, a 55-year-old male with a history of hypertension and hyperlipidemia who presents for follow up.	• Review the medical history form completed by the patient and vital signs obtained by clinical staff.	• Obtain an expended problem focused history (including response to treatment at last visit and reviewing interval correspondence or medical records received).* • Perform an expended problem focused examination.* • Consider relevant data, options, and risks and formulate a diagnosis and develop a treatment plan (low complexity medical decision making).* • Discuss diagnosis and treatment options with the patient. • Address the preventive health care needs of the patient. • Reconcile medication(s). • Write prescription(s). • Order and arrange diagnostic testing or referral as necessary.	• Complete the medical record documentation. • Handle (with the help of clinical staff) any treatment failures or adverse reactions to medications that may occur after the visit. • Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this office visit. • Receive and respond to any interval testing results or correspondence. • Revise treatment plan(s) and communicate with patient, as necessary. * Two of these three components required.

In order to ensure that these hospital discharge care coordination services are appropriately valued, we are seeking comment on the specific physician activities and the associated resources involved in physician provision of effective care coordination surrounding a hospital discharge. For the treating physician(s) overseeing the care of the beneficiary in the hospital, specific care coordination activities (for example, transfer of the beneficiary to a community physician) could include the following:

• Transitioning responsibility for the beneficiary's care to a receiving physician without a ''gap'' (that is, a seamless transition). This could include identifying the receiving physician by name and providing that physician's contact information to the beneficiary and/or family representative.

• Facilitating the transfer of ''core'' information to the receiving physician and/or beneficiary/family (if requested), via fax, secure e-mail, hard copy, or other mechanism. The core set of information could include (unless not applicable):

++ Important lab and diagnostic test results and drugs and treatments, as well as pending tests and how and when to obtain results.

++ Drugs prescribed, including planned changes.

++ Other treatments and tests prescribed, including planned changes.

++ Allergies.

++ Receiving physician contact information and specification of physician coverage for problems before any initial appointment. For hospitalized beneficiaries, this could include a planned initial post-discharge appointment within 7 business days with a physician, NP, or PA (if authorized by State law).

++ Overview of the caregiver situation.

++ Summary of beneficiary/family goals of care, with time frames and any restrictions.

++ Family caregiver and surrogate decision-maker identification, and assessment of needs (for the caregiver), as appropriate.

++ Responding to inquiries from the receiving physician or other provider (such as, LTCH, IRF, SNF) about the beneficiary's hospital stay and care plan in a timely and collaborative way.

For the beneficiary's primary physician(s) in the community overseeing the beneficiary's care post hospital discharge, specific care coordination activities could include:

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

• Notifying the patient that the receiving physician will be responsible for the beneficiary's care, and checking on the beneficiary's condition in the first few days after the transition.

• Obtaining and reviewing the core information provided by the sending physician.

• Contacting the physician(s) involved in the beneficiary's care during the hospital stay (as appropriate).

• Setting up an appointment for a face-to-face visit with the beneficiary, as appropriate.

We welcome comment on key physician activities associated with effective care coordination between the treating physician in the hospital and the beneficiary's primary physician in the community upon hospital discharge. We request public comment on the extent to which the clinical vignette for the hospital discharge and office visit codes appropriately incorporate hospital discharge care coordination activities. We also seek comment about whether the relative values assigned to these services under the physician fee schedule appropriately reflect the resources involved in performing activities that are essential to hospital discharge care coordination, and on ways to ensure appropriate recognition of the resources involved in these services, specifically, the physician time and complexity of physician work as well as the associated practice expenses. We also seek comments on the current coding structure for these services and on any other suggested changes to improve care coordination, particularly for the beneficiary's transition from the hospital to the community, to better reflect the resources required. We note that the Assistant Secretary of Planning and Evaluation (ASPE) in the Department of Health and Human Services hosted a technical expert panel in May 2011 identifying areas of additional research into equitable payment for services among specialties, with particular attention to valuing the resources required for primary care including generally identifying and valuing care coordination activities. We will consider the panel's discussion and any available analyses as we broadly consider physician payment for hospital discharge care coordination activities.

In addition to specific comments on the resources required for effective care coordination activities, we also broadly invite comment on other means to emphasize physician care coordination, such as educational efforts or the development of additional care coordination performance measures for the Physician Quality Reporting System and the Physician Fee Schedule Value Modifier.

A new trend in care transition planning is the use of shared care plans between beneficiary and physician rather than those created solely by the physician and dictated as ''doctor's orders'' to the beneficiary. Shared care plans are jointly developed between beneficiary and physician where the physician sets and documents self-management goals collaboratively with beneficiaries. These jointly developed care plans can be particularly important to improving overall beneficiary outcomes for beneficiaries with chronic illnesses, such as diabetes or HIV/AIDS, by developing a sense of personal responsibility for health outcomes. These plans give the patients a tool to learn about and practice principles of self-management, producing motivated and engaged beneficiaries. In addition, they provide health care professionals a communication tool to provide timely information that supports planned care and beneficiary self-management. (For more information see *http://www.innovations.ahrq.gov/content.aspx?id=2191* or *http://www.ihi.org/IHI/Topics/HIVAIDS/HIVDiseaseGeneral/Tools/My+Shared+Care+Plan.htm*.)

We will carefully weigh all comments received as we consider changes to the Medicare physician fee schedule to appropriately reflect the relative value of effective post discharge care coordination or other means to focus attention in this area. We note that we are not proposing any changes at this time. If we believe it would be appropriate to make certain changes, they would be proposed through future notice and comment rulemaking and would be subject to the budget neutrality requirements of section 1848(c)(2)(B)(ii)(II) of the Act.

L. Technical Corrections

1. Outpatient Speech-Language Pathology Services: Conditions and Exclusions

We are proposing a technical correction to the heading of the condition of coverage at § 410.62(b) for outpatient speech-language pathology services. The heading was inadvertently changed in the course of rulemaking for CY 2009 when a new paragraph was added at § 410.62(c) to recognize speech-language pathologists in private practice. The section heading at § 410.62(b) currently reads ''Special provisions for services furnished by speech-language pathologists in private practice.'' We are proposing to reinstate the correct heading at § 410.62(b) to read ''Condition for coverage of outpatient speech-language pathology services furnished to certain inpatients of a hospital or a CAH or SNF.''

2. Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

a. Proposed Changes to the Definition of Deemed Entity

We are proposing the following technical corrections to the definition of ''deemed entity'' in § 410.140:

• Removing the following phrases to clarify the purpose of the reference to an approved entity:

++ ''[B]y CMS to furnish and receive Medicare payment for the training''.

++ ''Upon being approved''.

++ ''CMS refers to this entity as an ''approved entity'' ''.

• Removing an incorrect reference to § 410.141(e) and replacing it with § 410.145(b).

The proposed revisions would read as follows:

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

b. Proposed Changes to the Condition of Coverage Regarding Training Orders

We are proposing the following technical correction to § 410.141(b)(1) entitled ''training orders'':

• Removing the cross-reference ''§ 410.32(a)'' and adding the cross-reference ''§ 410.32(a)(2)''.

• Removing the term ''it'' and adding the phrase ''the training'' in its place.

The proposed revisions would read as follows:

Training orders. Following an evaluation of the beneficiary's need for the training, the training is ordered by the physician (or qualified nonphysician practitioner) (as defined in § 410.32(a)(2)) treating the beneficiary's diabetes.

3. Practice Expense Relative Value Units (RVUs)

We are proposing the following technical corrections to the regulation at § 414.22(b):

• In paragraphs (b)(5)(i)(A) and (B)—

++ Include additional examples of the settings in which the facility or nonfacility practice expense (PE) RVUs are applied, respectively; and

++ Clarify that the lists of settings are not exhaustive; and amend these lists to include additional place of service examples.

• In paragraph (b)(5)(i)(A) we would add ''hospice'' to the list of places of service after ''community mental health center.

• In paragraph (b)(5)(i)(B)—

++ Revise the language to be more consistent with (b)(5)(i)(A) and to

include the ''comprehensive outpatient rehabilitation facility (CORF)'' as a place of service example; and

++ Clarify this provision by removing the text regarding the use of the nonfacility PE RVUs for services in ''* * * a facility or institution other than the hospital, skilled nursing facility, community mental health center, or ASC'' because this phrase does not accurately reflect the places of service where the nonfacility PE RVUs are applied.

• In paragraph (b)(5)(i)(C)—

++ Revise the paragraph introduction by adding ''and CORF'' after ''outpatient therapy'' and before ''services'' and, to more accurately define the term ''outpatient therapy services,'' to add ''(including physical therapy, occupational therapy and speech-language pathology services)'' after ''therapy services'' and before ''CORF services billed under * * *''.

The proposed revisions to § 414.22(b)(5)(i)(A), (B), and (C) would read as follows:

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

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.

The proposed rule imposes collection of information requirements as outlined in the regulation text and specified in various section of this proposed rule. However, this proposed rule also makes reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections, some of which have already received OMB approval.

A. Part B Drug Payment

The discussion of average sales price (ASP) issues in section IV.A.1 of this proposed rule with comment period pertains 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.

In order to facilitate more accurate and consistent ASP data reporting from manufacturers, we are proposing the following:

• To revise existing reporting fields and add new fields to the Addendum A template.

• To add a macro to the Addendum A template that will allow manufacturers to validate the format of their data prior to submission.

• To maintain a list of HCPCS codes for which manufacturer's report ASPs for NDCs on the basis of a specified unit.

• A clarification to existing regulation text at § 414.802. Current regulation text states that ''Unit means the product represented by the 11 digit National Drug Code.'' We propose to update the definition to account for situations when an alternative unit of reporting must be used.

Additionally, we will also be revising our instructions for the reporting of dermal grafting products in a user guide available on the ASP Web site at: Z*http://www.cms.gov/McrPartBDrugAvgSalesPrice/.*

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. The Addendum A template is currently approved under OMB control number 0938–0921. For the first year, we estimate that collection of the additional data elements will take approximately 2 additional hours for each submission of data, or 12 hours per response, at a cost of $252 per response. Based on the current number of respondents, we estimate that this requirement will affect approximately 180 manufacturers. Since manufacturers will respond 4 times per year, we estimate that, on an annual basis, the annual number of responses will be 720 (180 manufacturers multiplied by 4 responses) and the total annual hours burden will be 34,560 hours (720 annual responses multiplied by 48 annual hours per response). We estimate the annual cost burden to be $181,440 (cost per response multiplied by the annual number of responses). Once manufacturers adjust to the changes associated with electronic reporting after the first year, we anticipate that the burden estimate will decrease.

B. The Physician Quality Reporting System

Section IV.F.1. of this proposed rule discusses the background of the Physician Quality Reporting System, 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 2012 Physician Quality Reporting System, and the proposed criteria for satisfactory reporting in 2012.

With respect to satisfactory submission of data on quality measures by eligible professionals, eligible professionals include physicians, other practitioners as described in section 1842(b)(18)(c) of the Act, physical and occupational therapists, qualified speech-language pathologists, and qualified audiologists. Eligible professionals may choose whether to participate and, to the extent they satisfactorily submit data on quality measures for covered professional services, they can qualify to receive an incentive payment. To qualify to receive an incentive payment for 2012, we propose that the eligible professional (or group practice) would need to meet one of the criteria for satisfactory reporting described in section IV.F.1.e. or IV.F.1.f. of this proposed rule (or section IV.F.1.g. for group practices).

Because this is a voluntary program, it is difficult to accurately estimate how many eligible professionals would opt to participate in the Physician Quality Reporting System in CY 2012. Information from the ''Physician Quality

Reporting System 2009 Reporting Experience Report, ''which is available on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/pqrs,* indicates that eligible professionals from nearly 120,000 unique TIN/NPI combinations attempted to submit Physician Quality Reporting System quality measures data for the 2009 Physician Quality Reporting System. Therefore, for purposes of conducting a burden analysis for the 2012 Physician Quality Reporting System, we will assume that all eligible professionals who attempted to participate in the 2009 Physician Quality Reporting System will also attempt to participate in the 2012 Physician Quality Reporting System. Furthermore, we believe that the burden for eligible professionals who are participating in the Physician Quality Reporting System for the first time in 2012 would be considerably higher than the burden for eligible professionals who have participated in the Physician Quality Reporting System in prior years. As described later in this section, some preparatory steps are needed to begin participating in the Physician Quality Reporting System. To the extent that we are not proposing to retire the measures that an eligible professional has reported in a prior year and there are no changes to the measure's specifications from a prior year, such preparatory steps would not need to be repeated in subsequent years.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative would be the time and effort associated with eligible professionals identifying applicable Physician Quality Reporting System quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's or group practice's measures. We believe it is difficult to definitively quantify the burden because eligible professionals may have different processes for integrating the data collection for the Physician Quality Reporting System measures into their practice's work flows. Moreover, we expect that the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows would vary along with the number of measures that are potentially applicable to a given professional's practice. Since a majority of eligible professionals participate via claims or registry-based reporting of individual measures, they would generally be required to report on at least three measures to earn a Physician Quality Reporting System incentive. Therefore, we will assume that each eligible professional who attempts to submit Physician Quality Reporting System quality measures data via claims or registry reporting is attempting to earn a Physician Quality Reporting System incentive payment and reports on an average of three measures for this burden analysis.

Due to the fact that we have seen significant increases in participation each year since the program's inception, we anticipate even greater participation in the 2012 Physician Quality Reporting System than in previous years, including participation by eligible professionals who are participating in the Physician Quality Reporting System for the first time in 2012. As discussed previously, eligible professionals who are participating in the Physician Quality Reporting System for the first time in 2012 need to take preparatory steps to begin participating in the program. Since this burden analysis focuses on those new to the Physician Quality Reporting System, we will assign 5 hours as the amount of time needed for eligible professionals to review the 2012 Physician Quality Reporting System Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. This estimate is based on our assumption that an eligible professional would need up to 2 hours to review the 2012 Physician Quality Reporting System Measures List, review the reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications for up to 3 selected measures or up to 1 selected measures group and to develop a mechanism for incorporating reporting of the selected measures or measures group into the office work flows.

Information from the Physician Voluntary Reporting Program (PVRP), which was a predecessor to the Physician Quality Reporting System, indicated an average labor cost of $50 per hour for 2006. To account for salary increases over time, we will use an average practice labor cost of $60 per hour in our estimates based on an assumption of an average annual increase of approximately 3 percent. Thus, we estimate the cost for an eligible professional associated with preparing to report Physician Quality Reporting System quality measures would be approximately $300 per eligible professional ($60 per hour × 5 hours).

We continue to expect the ongoing costs associated with Physician Quality Reporting System participation to decline based on an eligible professional's familiarity with and understanding of the Physician Quality Reporting System, experience with participating in the Physician Quality Reporting System, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices. We also continue to expect the ongoing costs associated with Physician Quality Reporting System participation to decline as we align the participation requirements in the Physician Quality Reporting System with the reporting requirements in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program such that an eligible professional would only need to submit data to CMS one time for multiple purposes.

We believe the burden associated with actually reporting the Physician Quality Reporting System quality measures would vary depending on the reporting mechanism selected by the eligible professional. For the proposed claims-based reporting option, eligible professionals would need to 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 would collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). We do not anticipate any new forms and or any modifications to the existing transaction or form. We also do not anticipate changes to the 837–P or CMS Form 1500 for CY 2012.

Based on our experience with the 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 would 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 $60 per hour per practice, the cost associated with this burden would range from $0.25 in labor to about $12.00 in labor time for more complicated cases and/or measures,

with the cost for the median practice being $1.75.

The total estimated annual burden for this requirement would 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 Physician Quality Reporting System measures was 9. Since we proposed 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 will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional would be required to report quality measures data would vary, however, with the eligible professional's patient population and the types of measures on which the eligible professional chooses to report (each measure's specifications includes a required reporting frequency).

Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional associated with claims-based reporting would range from 4.5 minutes (0.25 minutes per measure × 3 measures × 6 cases per measure) to 180 minutes (12 minutes per measure × 3 measures × 6 cases per measure), with the burden to the median practice being 31.5 minutes (1.75 minutes per measure × 3 measures × 6 cases). We estimate the total annual reporting cost per eligible professional associated with claims-based reporting would range from $4.50 ($0.25 per measure × 3 measures × 6 cases per measure) to $216.00 ($12.00 per measure × 3 measures × 6 cases per measure), with the cost to the median practice being $31.50 per eligible professional ($1.75 per measure × 3 measures × 6 cases per measure).

For registry-based reporting, there would be no additional time burden for eligible professionals to report data to a registry as eligible professionals opting for registry-based reporting would more than likely already be reporting data to the registry for other purposes and the registry would merely be re-packaging the data for use in the Physician Quality Reporting System. Little, if any, additional data would need to be reported to the registry solely for purposes of participation in the 2012 Physician Quality Reporting System. However, eligible professionals would need to authorize or instruct the registry to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this would be approximately 5 minutes per eligible professional.

We are proposing that registries interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf in 2012 would need to complete a self-nomination process in order to be considered ''qualified'' to submit on behalf of eligible professionals unless the registry was qualified to submit on behalf of eligible professionals for prior program years and did so successfully. We estimate that the proposed self-nomination process for qualifying additional registries to submit on behalf of eligible professionals for the 2012 Physician Quality Reporting System would involve approximately 1 hour per registry to draft the letter of intent for self-nomination. We estimate that each self-nominated entity would also spend 2 hours for the interview with CMS officials and 2 hours calculating numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow. However, the time it takes to produce calculated numerators, denominators, and measure results using the CMS-provided measure flows could vary depending on the registry's experience and the number and type of measures for which the registry wishes to submit on behalf of eligible professionals. Additionally, part of the proposed self-nomination process involves the completion of an XML submission by the registry, which we estimate to take approximately 5 hours, but may vary depending on the registry's experience. We estimate that the registry staff involved in the registry self-nomination process would have an average labor cost of $50 per hour. Therefore, assuming the total burden hours per registry associated with the registry self-nomination process is 10 hours, we estimate that the total cost to a registry associated with the registry self-nomination process would be approximately $500 ($50 per hour × 10 hours per registry).

The burden associated with the proposed registry-based reporting requirements of the Physician Quality Reporting System would be the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants. We expect that the time needed for a registry to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures on their participants' behalf is would vary along with the number of eligible professionals reporting data to the registry and the number of applicable measures. However, we believe that registries already perform many of these activities for their participants. Therefore, there may not necessarily be a burden on a particular registry associated with calculating the measure results and submitting the measures results and numerator and denominator data on the quality measures to CMS on behalf of their participants. Whether there is any additional burden to the registry as a result of the registry's participation in the Physician Quality Reporting System would depend on the number of measures that the registry intends to report to CMS and how similar the registry's measures are to CMS' proposed Physician Quality Reporting System measures.

For EHR-Based reporting we have proposed for the CY 2012 Physician Quality Reporting System, the individual eligible professional could either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professionals' behalf. To submit data to CMS must directly from their EHR, the eligible professional would have to have access to a CMS-specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional has an account for this CMS-specified identity management system, he or she would need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. With respect to our proposed requirement for an eligible professional to submit a test file, we believe that doing so would take less than 1 hour. With respect to submitting the actual 2012 data file in 2013, we believe that this would take an eligible professional no more than 2 hours, depending on the number of patients on which the eligible professional is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional associated with submission of data on Physician Quality Reporting System quality measures should be minimal as all of the information required to report the measure should already reside in the

eligible professional's EHR. We did not introduce the EHR-Based reporting mechanism into the Physician Quality Reporting System until 2010. We are still in the process of analyzing 2010 data. As such, we believe it is difficult to predict how many eligible professionals may choose to participate in the 2012 Physician Quality Reporting System via the EHR-Based reporting mechanism.

We are proposing that an EHR vendor interested in having their product(s) be used by eligible professionals to submit the proposed Physician Quality Reporting System quality measures data to CMS or interested in submitting data obtained from an EHR to CMS on behalf of eligible professionals would be required to complete a self-nomination process in order for the vendor and/or its product(s) to be considered ''qualified'' for 2012. It is difficult to definitively quantify the burden associated with the proposed EHR self-nomination process as there is variation regarding the technical capabilities and experience among vendors. For purposes of this burden analysis, however, we estimate that the time required for an EHR vendor to complete the self-nomination process would be similar to the time required for registries to self-nominate, which is approximately 10 hours at $50 per hour for a total of $500 per EHR vendor ($50 per hour × 10 hours per EHR vendor).

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 for purposes of reporting 2012 Physician Quality Reporting System quality measures would be dependent on the EHR vendor's familiarity with the Physician Quality Reporting System, the vendor's system capabilities, as well as the vendor's programming capabilities. Some vendors already have these necessary capabilities and for such vendors, we estimate that the total burden hours would be 40 hours at a rate of $50 per hour for a total burden estimate of $2,000 ($50 per hour × 40 hours per vendor). However, given the variability in the capabilities of the vendors, we believe those vendors with minimal experience would have a burden of approximately 200 hours at $50 per hour, for a total estimate of $10,000 per vendor ($50 per hour × 200 hours per EHR vendor).

With respect to the proposed criteria for satisfactorily reporting data on the proposed quality measures for group practices to be treated as satisfactorily submitting quality measures data under the 2012 Physician Quality Reporting System discussed in section IV.F.1. of this proposed rule, group practices interested in participating in the 2012 Physician Quality Reporting System through the proposed group practice reporting option (GPRO) would need to complete a proposed self-nomination process similar to the proposed self-nomination process required of registries and EHR vendors. Therefore, assuming it takes 2 hours for a group practice to decide whether to participate as a group or individually, approximately 2 hours per group practice to draft the letter of intent for self-nomination, gather the requested information, and provide this requested information, and an additional 2 hours undergoing the vetting process with CMS officials, we estimate a total of 6 hours associated with the proposed self-nomination process. Assuming that the group practice staff involved in the group practice proposed self-nomination process have the same average practice labor cost as the average practice labor cost estimates we used for individual eligible professionals of $60 per hour, we estimate that the total cost to a group practice associated with the group practice self-nomination process would be approximately $360 ($60 per hour x 6 hours per group practice).

The burden associated with the proposed group practice reporting requirements of the 2012 Physician Quality Reporting System is the time and effort associated with the group practice submitting the proposed quality measures data. For practices participating under the proposed GPRO process, this would be the time associated with the physician group completing the data collection tool. The information collection components of this data collection tool have been reviewed by OMB and are currently approved under OMB control number 0938–0941, with an expiration date of December 31, 2011, for use in the Physician Group Practice, Medicare Care Management Performance (MCMP), and EHR demonstrations. Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a physician group completing the data collection tool would be approximately 79 hours per physician group. Based on an average labor cost of $60 per physician group, we estimate the cost of data submission per physician group associated with participating in the proposed 2012 Physician Quality Reporting System GPRO would be $4,740 ($60 per hour × 79 hours per group practice).

Eligible professionals who wish to qualify for the additional 0.5 percent incentive payment authorized under section 1848(m)(7) of the Act (''Additional Incentive Payments'') for 2012 would 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 2012. We believe that a majority of the eligible professionals who would attempt to qualify for this additional 0.5 percent incentive payment would be those who are already enrolled and participating in a Maintenance of Certification Board. The amount of time that it would take for the eligible professional to participate in the Maintenance of Certification Program more frequently than is required to qualify for or maintain board certification status would vary based on what each individual board determines constitutes ''more frequently.'' 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. Information from an informal poll of a few ABMS member boards indicates that the time an individual eligible professional spends to complete the practice assessment component of the Maintenance of Certification ranges from 8 to 12 hours.

We are seeking comments on this burden analysis, including the underlying assumptions used in developing our burden estimates.

C. Electronic Prescribing (eRx) Incentive Program

The eRx Incentive Program is a voluntary reporting program. In 2009, approximately 670,000 eligible professionals were eligible to participate in the eRx Incentive Program. Approximately 90,000 (or about 14 percent) of eligible professionals participated in the eRx Incentive Program in 2009. For purposes of participation in the eRx Incentive Program to earn an incentive payment, we expect that the number of eligible professionals participating in the eRx Incentive Program to be approximately 90,000, based on participation rates from the 2009 eRx Incentive Program.

Due to the implementation of the 2013 and 2014 payment adjustments as well as the proposals to expand the reporting mechanisms for purposes of

reporting the electronic prescribing measure for the 2013 and 2014 payment adjustments, we expect that there will be an increase in eligible professionals who participate in the eRx Incentive Program for CYs 2012 through 2014. Therefore, for purposes of conducting a burden analysis for the 2012 through 2014 eRx Incentive Program, we will assume that approximately 90,000 professionals eligible to participate in the 2009 eRx Incentive Program will participate. This is based on participation rates from the 2009 eRx Incentive Program, which is the highest participation level for the eRx Incentive Program we have yet recorded. As such, we can estimate that more than 90,000 unique TIN/NPI combinations will participate in the 2012, 2013, and 2014 eRx Incentive Program for purposes of the 2013 and 2014 payment adjustment (see the ''2009 Reporting Experience,'' which is available on the Physician Quality Reporting System section of the CMS Web site at *http://www.cms.hhs.gov/pqrs).* Although this estimate only accounts for approximately 13 percent of all professionals eligible to participate in the eRx Incentive Program, we believe that participation may be offset by the limitations and significant hardship exemptions we have proposed for the 2013 and 2014 payment adjustment.

Section IV.F.2. of this proposed rule discusses the background of the eRx Incentive Program. For the proposed programs for 2012 through 2014, eligible professionals and group practices may choose whether to participate and, to the extent they meet—(1) Certain proposed thresholds with respect to the volume of covered professional services furnished; and (2) the proposed criteria for being a successful electronic prescriber described in section IV.F.2.b.(2). of this proposed rule, they would qualify to receive an incentive payment for 2012 and 2013 and/or avoid being subject to the 2013 and 2014 payment adjustment.

In section IV.F.2.b.(2). of this proposed rule, we propose the requirements for eligible professionals and group practices can qualify for being a successful electronic prescriber in order to earn a 2012 and/or 2013 incentive payment. For the 2012 and 2013 incentives, as discussed in section IV.F.2. of this proposed rule, each eligible professional would need to report the electronic prescribing measure's numerator indicating that at least one prescription generated during an encounter was electronically submitted at least 25 instances during the reporting period in association with a denominator-eligible visit.

In section IV.F.2.b.(2). of this proposed rule, we propose additional requirements for eligible professionals and group practices can meet for the 2013 payment adjustment, as well as propose requirements for being a successful electronic prescriber for the 2014 payment adjustment. For the 2013 and 2014 payment adjustment, we propose that each eligible professional would need to report the electronic prescribing measure's numerator at least 10 instances during the reporting period.

We expect the ongoing costs associated with participation in the eRx Incentive Program to decline based on an eligible professional's understanding of the eRx Incentive Program, experience with participating in the eRx Incentive Program, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

Similar to the Physician Quality Reporting System, one factor in the burden to individual eligible professionals is the time and effort associated with individual eligible professionals reviewing the electronic prescribing measure to determine whether it is applicable to them, reviewing and selecting one of the available proposed reporting options (for purposes of the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments, this measure would be reportable through claims-based reporting, registry-based reporting, or through EHRs) and selecting one, gathering the required information, and incorporating reporting of the measure into their office work flows. Since the eRx Incentive Program consists of only 1 measure to report, we estimate 2 hours as the amount of time that would be needed for individual eligible professionals to prepare for participation in the eRx Incentive Program. At an average cost of approximately $60 per hour per practice, we estimate the total preparation costs to individual eligible professionals would be approximately $120 (2 hours × $60 per hour).

Another factor that we believe influences the burden to eligible professionals is how they choose to report the electronic prescribing measure. For eligible professionals who choose to do so via claims, we estimate that the burden associated with the requirements of this incentive program would be the time and effort associated with gathering the required information and identifying when it is appropriate to include the measure's quality data code (QDC) on the claims they submit for payment. For claims-based reporting, the measure's QDC would be collected as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500. We do not anticipate any new forms and or modifications to the existing transaction or form. We also do not anticipate changes to the 837–P or CMS Form 1500 for CY 2012.

Based on the information from the PVRP for the amount of time it takes a median practice to report one measure one time on claims (1.75 minutes) and our proposed requirement that eligible professionals report the measure 25 times for purposes of the incentive payment, we estimate the burden associated with claims-based data submission to would be 43.75 minutes (1.75 minutes per case × 1 measure × 25 cases per measure). This equates to a cost of approximately $43.75 (1.75 minutes per case × 1 measure × 25 cases per measure × $60 per hour) per individual eligible professional. For purposes of the 2013 and 2014 eRx payment adjustment, where we propose that an eligible professional is required to report the measure only 10 times, we estimate the burden associated with claims-based submission would be 17.5 minutes (1.75 minutes per case × 1 measure × 10 cases per measure). This equates to a cost of approximately $17.50 (1.75 minutes per case × 1 measure × 10 cases per measure × $60 per hour) per individual eligible professional.

Because registry-based reporting of the electronic prescribing measure to CMS was added to the eRx Incentive Program for 2010 and eligible professionals are not required to indicate to us how they plan to report the electronic prescribing measure each year, it is difficult to accurately estimate how many eligible professionals would opt to participate in the eRx Incentive Program through the proposed registry-based reporting mechanism in CYs 2012 through 2014. We do not anticipate, however, any additional burden for eligible professionals to report data to a registry as eligible professionals opting for registry-based reporting would more than likely already be reporting data to the registry for other purposes. Little, if any, additional data would need to be reported to the registry for purposes of participation in the 2012, 2013, and 2014 eRx Incentive Program since the only information that the registry would need to report to us is the number of times the eligible professional electronically prescribed. However, eligible professionals would need to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the

electronic prescribing measure to CMS on their behalf. We estimate that the time and effort associated with this would be approximately 5 minutes for each eligible professional that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf.

Based on our proposal to consider only registries qualified to submit Physician Quality Reporting System quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf for the 2012 and 2013 Physician Quality Reporting System reporting periods to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for the respective eRx Incentive Program reporting periods that occur in 2012 and 2013, there would be no need for a registry to undergo a separate self-nomination process for the eRx Incentive Program and therefore, no additional burden associated with the registry self-nomination process.

There would also be a burden to the registry associated with the registry calculating results for the electronic prescribing measure from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on the electronic prescribing quality measure to CMS on behalf of their participants. We expect that the time needed for a registry to review the electronic prescribing measure's specifications, calculate the measure's results, and submit the measure's results and numerator and denominator data on their participants' behalf would vary along with the number of eligible professionals reporting data to the registry. However, we believe that registries already perform many of these activities for their participants. Since the eRx Incentive Program consists of only one measure, we believe that the burden associated with the registry reporting the measure's results and numerator and denominator to CMS on behalf of their participants would be minimal.

For the proposed EHR-Based reporting mechanism, the eligible professional would need to either extract the necessary clinical data from his or her EHR and submit the necessary data to the CMS-designated clinical data warehouse or have an EHR data submission vendor extract the necessary clinical data from his or her EHR and submit the necessary data to CMS on the professional's behalf. Because this manner of reporting quality data to CMS was first added to the eRx Incentive Program in 2010 and eligible professionals are not currently required to (and we are not proposing to require that they) indicate to us how they intend to report the electronic prescribing measure, it is difficult to estimate how many eligible professionals would opt to participate in the eRx Incentive Program through the proposed EHR-Based reporting mechanism for reporting periods that occur in CYs 2012 and 2013. We believe that once an eligible professional's EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional associated with submission of data on the electronic prescribing measure should be minimal. The eligible professional who chooses to submit the electronic prescribing measure data directly to CMS from his or her EHR would have to have access to a CMS-specified identity management system, such as IACS, though. We believe it takes less than 1 hour to obtain access to the identity management system.

Since we are proposing that only EHR products and data submission vendors qualified for 2012 and 2013 Physician Quality Reporting System reporting periods could be used to submit data on the electronic prescribing measure for the respective eRx Incentive Program reporting periods that occur in CYs 2012 and 2013, there would be no need for EHR vendors and/or their products to undergo a separate self-nomination process for the eRx Incentive Program and therefore, no additional burden associated with the self-nomination process for the eRx Incentive Program.

There would also be a burden to the EHR vendor associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional and/or vendor would need to submit to CMS for purposes of reporting the proposed electronic prescribing measure. The time needed for an EHR vendor to review the measure's specifications and program its product to submit data on the measure to the CMS-designated clinical data warehouse would be dependent on the EHR vendor's familiarity with the electronic prescribing measure, the vendor's system capabilities, as well as the vendor's programming capabilities. Since we are proposing that only EHR products qualified for 2012 and 2013Physician Quality Reporting System reporting periods would qualify for the respective eRx Incentive Program reporting periods that occur in CY 2012 or 2013, and the eRx Incentive Program consists of only one measure, we believe that any burden associated with the EHR vendor to program its product(s) to submit data on the electronic prescribing measure to the CMS-designated clinical data warehouse would be minimal.

Finally, with respect to the proposed criteria for group practices to be treated as successful electronic prescribers for the 2012 and 2013 incentive, as well as with regard to the 2013 and 2014 payment adjustments, as discussed in section IV.F.2. of this proposed rule, respectively, group practices would have the same options as individual eligible professionals in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices would have the option of reporting the measure through claims, a qualified registry, or a qualified EHR product). There are only 2 differences between the proposed requirements for an individual eligible professional and a group practice: (1) The fact that a group practice would have to self-nominate; and (2) a difference in the number of times that a group practice would be required to report the electronic prescribing measure.

We do not anticipate any additional burden associated with the proposed group practice self-nomination process since we propose to limit the group practices to those selected to participate in the Physician Quality Reporting System GPRO. We are proposing that the practice only would need to indicate its desire to participate in the proposed eRx GPRO at the same time it self-nominates for the Physician Quality Reporting System GPRO and indicate how it intends to report the electronic prescribing measure.

In terms of the burden to group practices comprised of 25 to 99 eligible professionals associated with submission of the electronic prescribing measure, we believe that this would be similar to the burden to individual eligible professionals for submitting the electronic prescribing measure. In fact, overall, there could be less burden associated with a practice participating as a group rather than as individual eligible professionals because the total number of proposed reporting instances required by the group could be less than the total number of proposed reporting instances that would be required if each member of the group separately reported the electronic prescribing measure. Thus, we believe that the burden to a group practice associated with reporting the electronic prescribing measure could range from almost no burden (for groups who choose to do so through a qualified EHR or registry) to 18.22 hours (1.75 minutes per measure × 1 measure

× 625 cases per measure) for a group practice that chooses to report the electronic prescribing measures through the proposed claims submission process. Consequently, the total estimated cost per group practice to report the electronic prescribing measure could be as high as $1,093 ($1.75 per measure × 1 measure × 625 cases per measure).

In terms of the burden to group practices comprised of 100 or more eligible professionals associated with submission of the electronic prescribing measure, we believe that this would be similar to the burden to individual eligible professionals for submitting the electronic prescribing measure. In fact, overall, there could be less burden associated with a practice participating as a group rather than as individual eligible professionals because the total number of proposed reporting instances required by the group could be less than the total number of proposed reporting instances that would be required if each member of the group separately reported the electronic prescribing measure. Thus, we believe that the burden to a group practice associated with reporting the electronic prescribing measure could range from almost no burden (for groups who choose to do so through a qualified EHR or registry) to 72.92 hours (1.75 minutes per measure × 1 measure × 2,500 cases per measure) for a group practice that chooses to report the electronic prescribing measures through the proposed claims submission process. Consequently, the total estimated cost per group practice to report the electronic prescribing measure could be as high as $4,375 ($1.75 per measure × 1 measure × 2,500 cases per measure).

As with individual eligible professionals, we believe that group practices that choose to participate in the eRx GPRO through the proposed registry-based reporting mechanism of the electronic prescribing measure would more than likely already be reporting data to the registry. Little, if any, additional data would need to be reported to the registry for purposes of participation in the eRx Incentive Program for CYs 2012 through 2014 beyond authorizing or instructing the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf. We estimate that the time and effort associated with this proposed registry option would be approximately 5 minutes for each group practice that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf.

For group practices that choose to participate in the eRx Incentive Program for CYs 2012 through 2014 via the proposed EHR-Based reporting of the electronic prescribing mechanism, once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the group practice associated with submission of data on the electronic prescribing measure should be minimal.

We invite comments on this burden analysis, including the underlying assumptions used in developing our burden estimates.

D. Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals for the 2012 Payment Year

The EHR Incentive Program (discussed in section IV.H. of this proposed rule) is a voluntary program whereby eligible professionals (EPs) may earn an incentive payment for demonstrating meaningful use of certified EHR technology, which includes among other requirements, the submission of clinical quality measures (CQMs). The ''Electronic Health Record Incentive Program'' final rule (75 FR 44314 through 75 FR 44588) describes the CQMs and the CQM reporting mechanisms that will be available to EPs who choose to participate in the EHR Incentive Program (75 FR 44380) and established the criteria for achieving meaningful use in Stage 1, which includes CY 2012. In the final rule, for CY 2012, we estimated that approximately 385,954 Medicare EPs will be eligible to receive an incentive under the EHR Incentive Program (75 FR 44518). Section IV.H.2. of this proposed rule proposes changes to the EHR Incentive Program for EPs for the 2012 payment year. Aside from continuing the attestation method of reporting CQMs, we propose to allow the reporting of CQMs for purposes of demonstrating meaningful use through participation in the Physician Quality Reporting System—Medicare EHR Incentive Pilot. Eligible professionals may participate in the Pilot by submitting CQMs via (1) a Physician Quality Reporting System ''qualified'' EHR data submission vendor or (2) an EHR-Based reporting option using the EP's certified EHR technology, which must also be a Physician Quality Reporting System ''qualified'' EHR.

Because this is a voluntary program, EPs may choose whether to participate in the EHR Incentive Program and attest that they have met the meaningful use objectives and measures. Registration for the EHR Incentive Program opened in January 2011. At this time, we do not have sufficient data available on participation in the EHR Incentive Program by EPs to revise the final rule's estimate of how many EPs will opt to participate in the EHR Incentive Program for payment year 2012.

We believe the burden associated with actually reporting CQMs will vary depending on the reporting mechanism selected by the EP. Attestation to the objectives and measures is the only method available for EPs to demonstrate that they have met the meaningful use criteria in 2011. Attestation was first available on April 18, 2011 and we do not yet have sufficient data on the 2011 participation in the EHR Incentive Program. Therefore, it is difficult to estimate the level of participation in the proposed Pilot versus the number of EPs that would prefer to attest to the CQMs. However, we believe that the number of EPs who choose to participate via attestation will largely be those who are not participating in both the EHR Incentive Program and Physician Quality Reporting System. This is because EPs participating in the Physician Quality Reporting System would be more likely to participate in the Pilot.

As we estimated in the EHR Incentive Program final rule, we estimate that it would take 8 hours and 52 minutes for an EP to attest that during the EHR reporting period, the EP used certified EHR technology, specify the technology, and satisfied all Stage 1 meaningful use core criteria for payment year 2012 (75 FR 44518). We estimate that it will further take an additional 0.5 hours to select and attest to the clinical quality measures, in the format and manner specified by CMS (75 FR 44517).

For reporting via a qualified EHR data submission vendor, there would be no additional time burden for eligible professionals to report CQM data to a ''qualified'' EHR data submission vendor as EPs opting for this option would more than likely already be reporting data to the EHR data submission vendor for other purposes, such as the Physician Quality Reporting System, and the EHR data submission vendor would merely be re-packaging the data for use in the EHR Incentive Program. Furthermore, EPs more than likely would not need to authorize or instruct the EHR data submission vendor to submit CQM data to CMS on their behalf because this likely will have already been done as a requirement for reporting via an EHR data submission vendor under the Physician Quality Reporting System.

Qualified EHR data submission vendors interested in submitting CQM

data to CMS on their participants' behalf will not need to complete a self-nomination process in order to be considered ''qualified'' to submit on behalf of EPs as this process would have already been performed for the Physician Quality Reporting System. Therefore, we believe that there is no additional burden aside from the burden associated with being a Physician Qualified Reporting System qualified EHR data submission vendor for such vendors to submit CQMs on behalf of EPs.

For EPs who choose to participate in the pilot via direct data submission to CMS from the EP's certified her technology, an EP must have access to a CMS-specified identity management system, such as IACS, to participate in the Physician Quality Reporting System or eRx Incentive Program. We believe that EPs that choose the EHR-Based reporting pilot to report CQMs will do so only if they are participating in the Physician Quality Reporting System. As such, we believe there will be no additional burden on EPs to have access to a CMS-specified identity management system if the EP is already participating in the Physician Quality Reporting System. With respect to submitting the actual 2012 data file in 2013, we believe that this would take an EP no more than 2 hours, depending on the number of patients on which the EP is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS and the EP participates in the Physician Quality Reporting System, the additional burden to the EP associated with electronic submission of the CQMs should be minimal. Since this is a new, proposed reporting mechanism for the EHR Incentive Program 2012 payment year, it is difficult to predict the level of participation in EHR-Based reporting. However, we believe that the number of EPs who choose to participate in the EHR-Based reporting pilot will be the same as the number of eligible professionals who choose the EHR-Based reporting mechanism for the Physician Quality Reporting System. This is primarily because in addition to being certified EHR technology, the technology used under this reporting option would need to be ''qualified'' according to the Physician Quality Reporting System qualification process.

The burden associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the EP or vendor needs to submit to CMS for purposes of reporting CQMs will be dependent on the EHR vendor's familiarity with the EHR Incentive Program, the vendor's system capabilities, as well as the vendor's programming capabilities. As we already propose to require ''qualified'' EHRs vendors to perform these functions under the Physician Quality Reporting System, the burden for submitting CQMs under the EHR Incentive Program will be similar to the EHR vendor reporting burden under the Physician Quality Reporting System. For vendors who already have these necessary capabilities, we estimate the total burden hours to be 40 hours at a rate of $50 per hour for a total burden estimate of $2,000 ($50 per hour × 40 hours per vendor). However, given the variability in the capabilities of the vendors, those vendors with minimal experience would have a burden of approximately 200 hours at $50 per hour, for a total estimate of $10,000 per vendor ($50 per hour × 200 hours per EHR vendor).

We invite comments on this burden analysis, including the underlying assumptions used in developing our burden estimates.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at (410) 786–1326.

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–1524–P], Fax: (202) 395–5806; or E-mail: *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 Affordable Care Act and MIPPA and other statutory changes. This proposed rule is also necessary to make changes to the Part B drug payment policy and other Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis, that to the best of our ability presents the costs and benefits of the proposed rule. We solicit comment on the Regulatory Impact Analysis provided.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number 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 Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals

and States are not included in the definition of a small entity. The RFA requires that we analyze regulatory options for small businesses and other entities. A Regulatory Flexibility Act 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 provided here and throughout the preamble of this proposed rule constitutes our Initial Regulatory Flexibility Act (IRFA) analysis for the remaining provisions. This includes alternatives considered for the various proposed policies in this rule. We solicit public comment on the IRFA analysis provided.

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 before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. 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 implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services. 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. RVU Impacts

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

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

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2011 with proposed payment rates for CY 2012 using CY 2010 Medicare utilization for all years. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different than those shown in Table 64. 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, based 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.

Table 64 shows only the payment impact on PFS services. We note that these impacts do not include the effect of the January 2012 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 physician fee schedule payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. We currently estimate that the statutory formula used to determine the physician update will result in a CY 2012 conversion factor of $23.9635 which represents a PFS update of −29.5 percent. By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of the Congress. While the Congress has provided temporary relief from these reductions 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 physician fee schedule updates.

The following is an explanation of the information represented in Table 64:

- *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 2010 utilization and CY 2011 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 2012

impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to potentially misvalued codes. These impacts are primarily due to the multiple procedure payment reduction (MPPR) for the professional component of advanced imaging services.

• *Column D (Impact of PE RVU Changes—Full):* This column shows the estimated CY 2012 impact on total allowed charges of the changes in the PE RVUs if there were no remaining transition to the full use of the PPIS data.

• *Column E (Impact of PE RVU Changes—Tran):* This column shows the estimated CY 2012 impact on total allowed charges of the changes in the PE RVUs under the third year of the 4-year transition to the full use of the PPIS data. This column also includes the impact of the MPPR policy and, and the impact of changes due to potentially misvalued codes.

• *Column F (Combined Impact—Full):* This column shows the estimated CY 2012 combined impact on total allowed charges of all the changes in the previous columns if there were no remaining transition to the new PE RVUs using the PPIS data.

• *Column G (Combined Impact—Tran):* This column shows the estimated CY 2012 combined impact on total allowed charges of all the changes in the previous columns under the third year of the 4-year transition to the new PE RVUs using the PPIS data.

TABLE 64—CY 2012 PFS PROPOSED RULE TOTAL ALLOWED CHARGE ESTIMATED IMPACT FOR RVU AND MPPR CHANGES *

Specialty	Allowed charges (mil)	Impact of work and MP RVU changes	Impact of PE RVU changes		Combined impact	
			Full	Tran	Full	Tran
(A)	(B)	(C)	(D)	(E)	(F)	(G)
TOTAL	$83,014	0%	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	194	0%	1%	1%	1%	1%
ANESTHESIOLOGY	1,847	0%	4%	2%	4%	2%
CARDIAC SURGERY	384	0%	−2%	−1%	−2%	−1%
CARDIOLOGY	6,778	0%	−3%	−1%	−3%	−1%
COLON AND RECTAL SURGERY	146	0%	2%	1%	2%	1%
CRITICAL CARE	252	0%	1%	0%	1%	0%
DERMATOLOGY	2,931	0%	0%	0%	0%	0%
EMERGENCY MEDICINE	2,658	0%	−1%	−1%	−1%	−1%
ENDOCRINOLOGY	415	0%	1%	0%	1%	0%
FAMILY PRACTICE	5,640	0%	2%	1%	2%	1%
GASTROENTEROLOGY	1,837	0%	1%	0%	0%	0%
GENERAL PRACTICE	656	0%	2%	1%	2%	1%
GENERAL SURGERY	2,277	0%	1%	0%	1%	0%
GERIATRICS	200	0%	2%	1%	2%	1%
HAND SURGERY	121	0%	3%	1%	2%	1%
HEMATOLOGY/ONCOLOGY	1,912	0%	−1%	0%	−2%	0%
INFECTIOUS DISEASE	597	0%	1%	1%	1%	0%
INTERNAL MEDICINE	10,737	0%	1%	1%	1%	1%
INTERVENTIONAL PAIN MGMT	448	0%	3%	2%	2%	1%
INTERVENTIONAL RADIOLOGY	211	−1%	−3%	−1%	−4%	−2%
MULTISPECIALTY CLINIC/OTHER	84	1%	1%	1%	2%	1%
NEPHROLOGY	2,011	0%	0%	0%	0%	0%
NEUROLOGY	1,520	0%	4%	2%	4%	2%
NEUROSURGERY	669	0%	1%	0%	1%	0%
NUCLEAR MEDICINE	53	0%	−4%	−2%	−5%	−3%
OBSTETRICS/GYNECOLOGY	678	0%	0%	0%	0%	0%
OPHTHALMOLOGY	5,316	0%	3%	2%	3%	2%
ORTHOPEDIC SURGERY	3,572	0%	2%	1%	2%	1%
OTOLARNGOLOGY	1,001	0%	2%	1%	1%	1%
PATHOLOGY	1,122	0%	−2%	−1%	−2%	−1%
PEDIATRICS	68	0%	1%	1%	1%	1%
PHYSICAL MEDICINE	928	0%	3%	2%	3%	2%
PLASTIC SURGERY	339	0%	2%	1%	1%	0%
PSYCHIATRY	1,134	0%	0%	0%	0%	0%
PULMONARY DISEASE	1,758	0%	1%	0%	1%	0%
RADIATION ONCOLOGY	1,968	0%	−8%	−4%	−8%	−4%
RADIOLOGY	4,722	−1%	−5%	−2%	−6%	−4%
RHEUMATOLOGY	530	0%	0%	0%	0%	0%
THORACIC SURGERY	371	0%	−2%	−1%	−1%	−1%
UROLOGY	1,919	0%	−3%	−2%	−3%	−2%
VASCULAR SURGERY	749	0%	−2%	−1%	−2%	−1%
AUDIOLOGIST	56	0%	−6%	−3%	−6%	−3%
CHIROPRACTOR	743	0%	2%	1%	2%	1%
CLINICAL PSYCHOLOGIST	559	0%	−5%	−3%	−5%	−3%
CLINICAL SOCIAL WORKER	386	0%	−6%	−3%	−6%	−3%
DIAGNOSTIC TESTING FACILITY	833	0%	−8%	−2%	−8%	−3%
INDEPENDENT LABORATORY	1,047	0%	−3%	−1%	−3%	−1%
NURSE ANES/ANES ASST	769	0%	5%	2%	5%	2%
NURSE PRACTITIONER	1,376	0%	2%	1%	2%	1%
OPTOMETRY	980	0%	4%	2%	4%	2%

TABLE 64—CY 2012 PFS PROPOSED RULE TOTAL ALLOWED CHARGE ESTIMATED IMPACT FOR RVU AND MPPR CHANGES *—Continued

Specialty	Allowed charges (mil)	Impact of work and MP RVU changes	Impact of PE RVU changes		Combined impact	
			Full	Tran	Full	Tran
(A)	(B)	(C)	(D)	(E)	(F)	(G)
ORAL/MAXILLOFACIAL SURGERY	43	0%	2%	1%	2%	1%
PHYSICAL/OCCUPATIONAL THERAPY	2,324	0%	5%	3%	5%	3%
PHYSICIAN ASSISTANT	1,055	0%	1%	0%	1%	0%
PODIATRY	1,902	0%	3%	2%	3%	2%
PORTABLE X-RAY	97	0%	4%	3%	4%	3%
RADIATION THERAPY CENTERS	73	0%	−9%	−5%	−9%	−5%
OTHER	17	0%	5%	4%	5%	4%

*Table 64 shows only the payment impact on PFS services. We note that these impacts do not include the effects of the January 2012 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 third 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 third year of the transition are generally consistent with the impacts that would be expected based on the impacts displayed in the CY 2011 final rule with comment period.

The second general factor contributing to the CY 2012 impacts shown in Table 64 is a secondary effect of the CY 2011 rescaling of the RVUs so that, in the aggregate, they match the work, PE, and malpractice proportions in the revised and rebased MEI for CY 2011. That is, the rebased MEI had a greater proportion attributable to malpractice and PE and, correspondingly, a lesser proportion attributable to work. Specialties that have a high proportion of total RVUs attributable to work, such as emergency medicine, experienced a decrease in aggregate payments as a result of this rescaling, while specialties that have a high proportion attributable to PE, such as diagnostic testing facilities, experienced an increase in aggregate payments. (For further details on the MEI rebasing, see the discussion beginning on 75 FR 73262 in the CY 2011 PFS final rule.)

Table 64 also includes the impacts resulting from our proposal to expand the current 50 percent MPPR policy to the professional component of advanced imaging services. We estimate that this policy would redistribute approximately $100 million through a small increase in the conversion factor and a small adjustment to all PE RVUs. We estimate that this change would primarily reduce payments to the specialties of radiology and interventional radiology. Finally, Table 64 also reflects the impacts of our proposed adjustments to improve the accuracy of the time associated with the work RVUs for certain services, including group therapy services, as discussed previously in section II.A. of this proposed rule.

b. Combined Impact

Column F of Table 64 displays the estimated CY 2012 combined impact on total allowed charges by specialty of all the proposed RVU and MPPR changes. These impacts range from an increase of 5 percent for nurse anesthetists to a decrease of 9 percent for radiation therapy centers. Again, these impacts are estimated prior to the application of the negative CY 2012 Conversion Factor (CF) update applicable under the current statute.

Table 65 shows the estimated impact on total payments for selected high-volume procedures of all of the changes discussed previously. We have included CY 2012 payment rates with and without the effect of the CY 2012 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.

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TABLE 65: IMPACT OF PROPOSED RULE AND ESTIMATED PHYSICIAN UPDATE ON CY 2012 PAYMENT FOR SELECTED PROCEDURES

CPT/ HCPCS[1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)	CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)
11721		Debride nail 6 or more	$25.82	$25.17	-3%	$17.73	-31%	$41.79	$41.83	0%	$29.48	-29%
17000		Destruct premalg lesion	$55.38	$55.44	0%	$39.06	-29%	$79.50	$79.92	1%	$56.31	-29%
27130		Total hip arthroplasty	$1,440.26	$1,437.28	0%	$1,012.70	-30%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,224.51	$1,223.69	0%	$862.21	-30%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,539.47	$1,535.22	0%	$1,081.71	-30%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,984.22	$1,942.33	-2%	$1,368.56	-31%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,128.70	$1,108.74	-2%	$781.21	-31%	NA	NA	NA	NA	NA
43239		Upper gi endoscopy biopsy	$174.64	$173.45	-1%	$122.21	-30%	$345.20	$346.22	0%	$243.95	-29%
66821		After cataract laser surgery	$296.95	$303.71	NA	$213.99	-28%	$314.62	$321.74	2%	$226.69	-28%
66984		Cataract surg w/iol 1 stage	$742.38	$753.67	2%	$531.03	-28%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$647.59	$657.08	1%	$462.97	-29%	$669.00	$678.85	1%	$478.31	-29%
71010		Chest x-ray	NA	NA	NA	NA	NA	$23.78	$23.47	-1%	$16.53	-30%
71010	26	Chest x-ray	$8.83	$8.84	0%	$6.23	-29%	$8.83	$8.84	0%	$6.23	-29%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$110.76	$110.19	-1%	$77.64	-30%
77056	26	Mammogram both breasts	$43.49	$42.17	-3%	$29.71	-32%	$43.49	$42.17	-3%	$29.71	-32%
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.20	$79.92	-2%	$56.31	-31%
77057	26	Mammogram screening	$35.00	$34.01	-3%	$23.96	-32%	$35.00	$34.01	-3%	$23.96	-32%
77427		Radiation tx management x5	$180.41	$174.81	-3%	$123.17	-32%	$180.41	$174.81	-3%	$123.17	-32%
88305	26	Tissue exam by pathologist	$36.35	$35.71	-2%	$25.16	-31%	$36.35	$35.71	-2%	$25.16	-31%
90801		Psy dx interview	$123.33	$119.38	-3%	$84.11	-32%	$153.91	$151.35	-2%	$106.64	-31%
90862		Medication management	$44.85	$44.21	-1%	$31.15	-31%	$57.76	$58.16	1%	$40.98	-29%
90935		Hemodialysis one evaluation	$74.75	$72.44	-3%	$51.04	-32%	NA	NA	NA	NA	NA
92012		Eye exam established pat	$50.62	$51.36	1%	$36.18	-29%	$79.84	$81.62	2%	$57.51	-28%
92014		Eye exam & treatment	$77.13	$77.88	1%	$54.88	-29%	$115.86	$118.36	2%	$83.39	-28%
92980		Insert intracoronary stent	$873.19	$834.95	-4%	$588.30	-33%	NA	NA	NA	NA	NA
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$19.71	$18.71	-5%	$13.18	-33%
93010		Electrocardiogram report	$8.83	$8.50	-4%	$5.99	-32%	$8.83	$8.50	-4%	$5.99	-32%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$92.42	$87.41	-5%	$61.59	-33%
93307	26	Tte w/o doppler complete	$47.57	$45.91	-3%	$32.35	-32%	$47.57	$45.91	-3%	$32.35	-32%
93458	26	L hrt artery/ventricle angio	$320.06	$315.96	-1%	$222.62	-30%	$320.06	$315.96	-1%	$222.62	-30%
98941		Chiropractic manipulation	$30.92	$30.61	-1%	$21.57	-30%	$35.34	$35.71	1%	$25.16	-29%
99203		Office/outpatient visit new	$74.75	$74.48	0%	$52.48	-30%	$102.95	$104.41	1%	$73.57	-29%
99213		Office/outpatient visit est	$49.27	$49.66	1%	$34.99	-29%	$68.97	$69.72	1%	$49.13	-29%
99214		Office/outpatient visit est	$75.77	$75.84	0%	$53.44	-29%	$102.27	$103.05	1%	$72.61	-29%
99222		Initial hospital care	$132.17	$132.64	0%	$93.46	-29%	NA	NA	NA	NA	NA

CPT/ HCPCS[1]	MOD	Short Descriptor	Facility					Nonfacility				
			CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)	CY 2011[2]	CY 2012[3] (pre-update)	% Change (pre-update)	CY 2012[4]	% Change (post-update)
99223		Initial hospital care	$194.01	$194.88	0%	$137.31	-29%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.39	$38.09	-1%	$26.84	-30%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$69.31	$69.38	0%	$48.89	-29%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$99.55	$99.65	0%	$70.21	-29%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$214.05	$184.34	-14%	$129.88	-39%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$101.25	$102.37	1%	$72.13	-29%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$61.16	$59.86	-2%	$42.18	-31%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$115.52	$114.27	-1%	$80.52	-30%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.11	$216.65	0%	$152.65	-30%	$264.34	$265.28	0%	$186.92	-29%
99292		Critical care addl 30 min	$109.06	$108.83	0%	$76.68	-30%	$118.92	$118.70	0%	$83.63	-30%
99348		Home visit est patient	NA	NA	NA	NA	NA	$82.22	$81.62	-1%	$57.51	-30%
99350		Home visit est patient	NA	NA	NA	NA	NA	$169.54	$170.39	1%	$120.06	-29%
G0008		Immunization admin	NA	NA	NA	NA	NA	$23.10	$23.81	3%	$16.77	-27%

1 CPT codes and descriptions are copyright 2010 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
2 Payments based on the 2011 conversion factor of 33.9764
3 Payments based on the 2011 conversion factor of 33.9764, adjusted to 34.0103 to include the budget neutrality adjustment.
4 Payments based on the 2012 conversion factor of 23.9635, which includes the budget neutrality adjustment.

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D. Effects of Proposal To Review Potentially Misvalued Codes on an Annual Basis Under the PFS

This year's proposal of a process to consolidate the Five-Year Reviews of Work and PE RVUs with the annual review of potentially misvalued codes, as discussed in section II.B.3. of this proposed rule with comment period, is not anticipated to have a budgetary impact in CY 2012. As noted previously, to the extent that for CY 2012 we have proposed revised RVUs for codes identified under the potentially misvalued codes initiative, Table 64 includes the estimated CY 2012 impact on total allowed charges of the changes in the RVUs for these codes.

E. Effect of Proposed Revisions to Malpractice RUVs

As discussed in section II.D.2. of this proposed rule, we proposed to revise malpractice RVUs for a limited number of codes. The utilization of many of these services is 0, while the others have a very low utilization. Therefore, we estimate no significant budgetary impact from the proposed changes to the MP RVUs due to the very low utilization of these services.

F. Effect of Proposed Changes to Geographic Practice Cost Indices (GPCIs)

As discussed in section II.E. of this proposed rule, we are required to update the GPCI values 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 2012, we are proposing to revise the PE GPCIs for each Medicare locality, as well as the cost share weights for all three GPCI components. Moreover, the proposed revised PE GPCI values are a result of our analysis of the PE methodology as required by section 1848(e)(1)(H)(iv) of the Act. The new GPCIs rely upon the 2006–2008 American Community Survey (ACS) data for determining the relative cost differences in the office rent component of the PE GPCIs. In addition, we utilized 2006 through 2008 Bureau of Labor Statistics (BLS) and Occupational Employment Statistics (OES) data to determine the employee compensation component with data specific to the offices of physicians industry. Finally, we proposed to create a purchased services index that will be used to geographically adjust for differences in the labor-related share of the industries occupying the ''All Other Services'' and ''Other Professional Expenses'' 2006-based MEI categories.

To determine the cost share weights for the proposed CY 2012 PE GPCIs, we used the 2006-based MEI weight for the PE category of 51.734 percent minus the professional liability insurance category weight of 4.295 percent. Therefore, we propose a cost share weight for the PE GPCIs of 47.439 percent. For the employee compensation portion of the PE GPCIs, we used the non-physician employee compensation category weight of 19.153 percent. The fixed capital and utilities MEI categories were combined to achieve a total office rent weight of 10.223 percent. As discussed in the previous paragraph, a new purchased services index was created to geographically adjust the labor-related components of the ''All Other Services'' and ''Other Professional Expenses'' categories of the MEI. In order to calculate the purchased services index, we are proposing to merge the corresponding weights of these two categories to form a combined purchased services weight of 8.095. However, since our proposed purchased services methodology only accounts for the labor related share of the industries comprising the ''All Other Services'' and ''Other Professional Expenses'' categories, only 5.011 percentage points of the 8.095 percentage points accounting for the purchased services cost share weight is adjusted for locality cost differences. We are proposing a cost share weight for the medical equipment, supplies, and other miscellaneous expenses component of 9.968 percent. Furthermore, the physician compensation cost category and its weight of 48.266 percent reflects the proposed work GPCI cost share weight and the professional liability insurance weight of 4.295 percent was used for the malpractice GPCI cost share weight. A more detailed discussion on the proposed CY 2012 GPCI cost share weights can be found in section II.E. of this proposed rule.

Additionally, section 1848(e)(1)(E) of the Act (as amended by section 103 of the Medicare and Medicaid Extenders Act of 2010) extended the 1.000 work GPCI floor through December 31, 2011. Therefore, the CY 2012 GPCIs reflect the sunset of the 1.000 work GPCI floor. Section 1848(e)(1)(G) of the Act (as amended by section 134(b) of the MIPPA) established a permanent 1.500 work GPCI floor in Alaska, beginning January 1, 2009 and, therefore, the 1.500 work GPCI floor in Alaska will remain in place for CY 2012. Moreover, section 1848(e)(1)(I) of the Act (as added by section 10324(c) of the Affordable Care Act) established a permanent 1.000 PE GPCI floor for services furnished in frontier States effective January 1, 2011.

Addendum D to this proposed rule shows the estimated effects of the revised GPCIs on locality GAFs for CY 2012. The GAFs reflect the use of revised GPCI data and the updated cost share weights. The GAFs are a weighted composite of each area's work, PE, and malpractice GPCIs using the national GPCI cost share weights. While we do not actually use the GAFs in computing the PFS payment for a specific service, they are useful in comparing the estimated overall costs and payments for different localities. The cumulative effects of all of the GPCI revisions, including the updated underlying GPCI data, updated cost share weights, and provisions of the Affordable Care Act, are reflected in the CY 2012 GPCI values that are displayed in Addendum E in this proposed rule.

The following Table 66 illustrates the impact by physician fee schedule geographic locality of moving from the current law CY 2011 Geographic Adjustment Factors (GAFs) to the proposed CY 2012 GAFs. The GAFs summarize the combined impact of the three separate GPCIs into a single number to more easily compare the impact of policy changes among localities. More specifically, the GAF for a locality is the weighted average of the individual work, practice expense, and malpractice. The table first shows the impact under current law and regulation, and then with the additional impact of our recommendations. As shown in the table, the primary driver of the CY 2012 impact is the current law expiration of the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the Medicare and Medicaid Extenders Act. The table is sorted by total impact from largest reductions to largest increases. When the overall impacts directly resulting from our proposed changes to the PE GPCI are isolated, the impacts are negligible (Column F). The following is an explanation of the information represented in Table 66:

- *Column (A):* Medicare Locality—The PFS geographic locality.
- *Column (B):* CY 2011 GAF—The current CY 2011 Geographic Adjustment Factor for the locality, which includes the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the Medicare and Medicaid Extenders Act. These figures also reflect the first year of the two-year transition to the latest GPCIs that began in 2011.
- *Column (C):* CY 2012 GAF (Current Law/Reg)—The CY 2012 Geographic

Adjustment Factor for the locality under current law and regulations, which includes the expiration of the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the MMEA. These numbers also reflect the end of the transition to the latest GPCIs that began in 2011.

• *Column (D):* CY 2012 GAF (Proposed NPRM)—The CY 2012 Geographic Adjustment Factor for the locality under the recommended NPRM proposals. The two largest drivers are the proposed use of residential rent data from the Census Bureau's ACS data instead of the Department of Housing and Urban Development's HUD FMR data, and the proposed benchmarking of the GPCI practice expense weights to the 2006-based MEI cost share weights. The Geographic Adjustment Factors in this column are for 2012 and do not reflect any temporary increases to work and practice expense required by the Affordable Care Act.

• *Column (E):* Percent Change CY 2011 to CY 2012 (current)—Impact of the expiration of the non-budget neutral increases to the CY 2011 GPCIs for lower expense areas authorized by the Affordable Care Act and the MMEA and the end of the transition to the latest GPCIs that began in 2011.

• *Column (F):* Percent Change CY 2012 (No NPRM) to CY 2012 (NPRM)—Impact of the four regulatory changes described previously.

• *Column (G):* Percent Change Combined Impact CY 2011 to CY 2012—Combined impact of all changes from CY 2011 to CY 2012.

TABLE 66—CY 2012 GEOGRAPHIC ADJUSTMENT FACTORS (GAFS) CHANGES UNDER CURRENT LAW AND THE PROPOSED RULE

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Medicare locality	CY 2011 GAF	CY 2012 GAF (current law/reg)	CY 2012 GAF (proposed)	% Change CY 2011 to CY 2012 (current) Col (C)/Col (B)	% Change CY 2012 (curr) to CY 2012 (proposed rule) Col (D)/Col (C)	% Change combined impact CY 2011 to CY 2012 Col (D)/Col (B)
PUERTO RICO	0.903	0.786	0.769	−13	−2	−15
WEST VIRGINIA	0.972	0.910	0.909	−6	0	−6
OKLAHOMA	0.955	0.904	0.897	−5	−1	−6
MISSISSIPPI	0.961	0.910	0.907	−5	0	−6
REST OF MISSOURI	0.961	0.903	0.908	−6	1	−6
ARKANSAS	0.945	0.893	0.895	−6	0	−5
REST OF LOUISIANA	0.965	0.914	0.914	−5	0	−5
IOWA	0.950	0.898	0.902	−5	0	−5
BEAUMONT, TX	0.978	0.925	0.932	−5	1	−5
KENTUCKY	0.959	0.917	0.914	−4	0	−5
ALABAMA	0.949	0.905	0.907	−5	0	−4
TENNESSEE	0.959	0.918	0.918	−4	0	−4
NEBRASKA	0.947	0.905	0.909	−4	0	−4
REST OF MAINE	0.961	0.922	0.923	−4	0	−4
IDAHO	0.959	0.926	0.923	−3	0	−4
KANSAS	0.964	0.923	0.928	−4	1	−4
SOUTH CAROLINA	0.959	0.925	0.924	−4	0	−4
INDIANA	0.966	0.928	0.932	−4	0	−4
REST OF TEXAS	0.973	0.934	0.939	−4	1	−3
REST OF GEORGIA	0.970	0.936	0.937	−4	0	−3
METROPOLITAN BOSTON	1.106	1.079	1.069	−2	−1	−3
NORTH CAROLINA	0.970	0.934	0.938	−4	0	−3
UTAH	0.982	0.946	0.950	−4	0	−3
MANHATTAN, NY	1.153	1.142	1.119	−1	−2	−3
REST OF PENNSYLVANIA	0.986	0.957	0.957	−3	0	−3
NEW ORLEANS, LA	1.005	0.980	0.977	−2	0	−3
SOUTH DAKOTA**	0.978	0.952	0.951	−3	0	−3
LOS ANGELES, CA	1.106	1.099	1.076	−1	−2	−3
REST OF ILLINOIS	0.985	0.950	0.959	−4	1	−3
NEW MEXICO	0.979	0.949	0.955	−3	1	−2
REST OF MICHIGAN	0.985	0.962	0.962	−2	0	−2
ALASKA*	1.289	1.289	1.260	0	−2	−2
VENTURA, CA	1.113	1.105	1.090	−1	−1	−2
REST OF NEW YORK	0.965	0.948	0.946	−2	0	−2
OHIO	0.992	0.970	0.974	−2	0	−2
METROPOLITAN KANSAS CITY, MO	0.996	0.975	0.978	−2	0	−2
MONTANA**	0.996	0.976	0.978	−2	0	−2
CONNECTICUT	1.094	1.086	1.075	−1	−1	−2
NORTH DAKOTA**	0.979	0.964	0.963	−2	0	−2
ANAHEIM/SANTA ANA, CA	1.129	1.129	1.111	0	−2	−2
REST OF FLORIDA	1.014	0.996	0.999	−2	0	−1
NYC SUBURBS/LONG I., NY	1.161	1.159	1.144	0	−1	−1
SAN MATEO, CA	1.199	1.194	1.183	0	−1	−1
EAST ST. LOUIS, IL	1.016	0.997	1.003	−2	1	−1
REST OF MASSACHUSETTS	1.040	1.039	1.028	0	−1	−1
REST OF OREGON	0.968	0.950	0.958	−2	1	−1
HAWAII	1.074	1.091	1.063	2	−3	−1

TABLE 66—CY 2012 GEOGRAPHIC ADJUSTMENT FACTORS (GAFS) CHANGES UNDER CURRENT LAW AND THE PROPOSED RULE—Continued

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Medicare locality	CY 2011 GAF	CY 2012 GAF (current law/ reg)	CY 2012 GAF (proposed)	% Change CY 2011 to CY 2012 (current) Col (C)/Col (B)	% Change CY 2012 (curr) to CY 2012 (proposed rule) Col (D)/Col (C)	% Change combined impact CY 2011 to CY 2012 Col (D)/Col (B)
ARIZONA	0.989	0.977	0.979	−1	0	−1
SAN FRANCISCO, CA	1.198	1.194	1.186	0	−1	−1
WISCONSIN	0.965	0.949	0.956	−2	1	−1
METROPOLITAN ST. LOUIS, MO	0.988	0.971	0.979	−2	1	−1
FORT WORTH, TX	0.991	0.981	0.982	−1	0	−1
VERMONT	0.982	0.980	0.974	0	−1	−1
NORTHERN NJ	1.120	1.105	1.112	−1	1	−1
AUSTIN, TX	0.992	0.979	0.985	−1	1	−1
MIAMI, FL	1.108	1.100	1.101	−1	0	−1
SOUTHERN MAINE	0.997	0.993	0.991	0	0	−1
WYOMING**	1.002	0.994	0.996	−1	0	−1
HOUSTON, TX	1.008	0.992	1.002	−2	1	−1
METROPOLITAN PHILADELPHIA, PA	1.068	1.062	1.062	−1	0	−1
VIRGINIA	0.978	0.971	0.974	−1	0	0
DETROIT, MI	1.060	1.047	1.056	−1	1	0
OAKLAND/BERKELEY, CA	1.133	1.136	1.130	0	−1	0
REST OF NEW JERSEY	1.074	1.066	1.072	−1	1	0
BRAZORIA, TX	0.996	0.977	0.995	−2	2	0
DC + MD/VA SUBURBS	1.124	1.125	1.123	0	0	0
RHODE ISLAND	1.042	1.039	1.042	0	0	0
MARIN/NAPA/SOLANO, CA	1.119	1.127	1.120	1	−1	0
DELAWARE	1.012	1.010	1.013	0	0	0
DALLAS, TX	1.004	0.997	1.005	−1	1	0
VIRGIN ISLANDS	0.998	0.997	1.000	0	0	0
FORT LAUDERDALE, FL	1.061	1.062	1.064	0	0	0
POUGHKEEPSIE/N NYC SUBURBS, NY	1.037	1.039	1.040	0	0	0
ATLANTA, GA	1.002	0.997	1.005	0	1	0
QUEENS, NY	1.140	1.150	1.144	1	−1	0
CHICAGO, IL	1.081	1.076	1.085	0	1	0
NEW HAMPSHIRE	1.007	1.012	1.011	0	0	0
GALVESTON, TX	0.997	0.995	1.002	0	1	1
COLORADO	0.989	0.990	0.994	0	0	1
MINNESOTA	0.969	0.968	0.974	0	1	1
REST OF CALIFORNIA	1.025	1.038	1.033	1	0	1
REST OF WASHINGTON	0.987	0.985	0.997	0	1	1
NEVADA**	1.024	1.031	1.037	1	1	1
SUBURBAN CHICAGO, IL	1.061	1.059	1.077	0	2	2
BALTIMORE/SURR. CNTYS, MD	1.052	1.070	1.069	2	0	2
REST OF MARYLAND	1.004	1.024	1.021	2	0	2
PORTLAND, OR	0.991	0.995	1.009	0	1	2
SANTA CLARA, CA	1.156	1.164	1.179	1	1	2
SEATTLE (KING CNTY), WA	1.045	1.056	1.077	1	2	3

* GAF reflects a 1.5 work GPCI floor in Alaska established by the MIPPA.
** GAFs reflect a 1.0 PE GPCI floor for frontier States as required by the Affordable Care Act.

G. Effects of Proposed Changes to Medicare Telehealth Services Under the Physician Fee Schedule

As discussed in section III.D. of this proposed rule, we are proposing to add several new codes to the list of telehealth services and revise the criteria for adding services to the list of 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 budgetary impact from the proposed additions. In addition, the proposed revision to the telehealth criteria would be effective for CY 2013 PFS telehealth services, with no impact in CY 2012.

H. Effects of the Impacts of Other Provisions of the Proposed Rule

1. Part B Drug Payment: ASP Issues

Application of our proposals for ''ASP Reporting Template Update'' and ''Reporting of ASP Units and Sales Volume for Certain Products,'' as discussed in section IV.A. of this proposed rule involve revisions to the existing ASP reporting template which will facilitate the accuracy and efficiency of data transfer from manufacturers. Any impacts are dependent on the status and quality of quarterly manufacturer data submissions, so we cannot quantify associated savings.

Finally, as discussed in section IV.A. of this proposed rule, we are proposing to provide for appropriate price substitutions that account for market-related pricing changes and would allow Medicare to pay based off lower

market prices for those drugs and biologicals that consistently exceed the applicable threshold percentage. Based on estimates published in various OIG reports (see section IV.A. for a list of citations), 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.

2. Chiropractic Services Demonstration

As discussed in section IV.B. of this proposed rule, we are continuing the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the budget neutrality requirement in section 651(f)(1)(b) of the MMA. We initiated this recoupment in CY 2010 and this will be the third 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 CYs 2010 through 2014. To implement this required budget neutrality adjustment, we are recouping $10 million in CY 2012 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.

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

As discussed in section IV.D. of this proposed rule, we are proposing to implement the provision that specifies that for services furnished after December 31, 2011, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient. The savings associated with implementing this provision are estimated to be approximately 80 million dollars for CY 2012.

4. Section 4103: Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan: Incorporation of a Health Risk Assessment as Part of the Annual Wellness Visit

As discussed in section IV.E. of this proposed rule, section 1861(s)(2)(FF) of the Act, as described more fully in section 1861(hhh), of the Act (as added by section 4103 of the Affordable Care Act) provides Medicare coverage for an annual wellness visit. Regulations for Medicare coverage of the AWV are established at 42 CFR 410.15. The annual wellness visit is covered with no coinsurance or deductible when furnished by a Medicare participating provider (a health professional as that term is defined in 42 CFR 410.15). The annual wellness visit entails the creation of a personalized prevention plan for an individual and includes elements, such as updating medical and family history, identifying providers that regularly provide medical care to the individual, measurement of height, weight, and body mass index, identification of risk factors, the provision of personalized health advice, and development of a screening schedule (such as a checklist), and referrals as appropriate for additional preventive services. Section 1861(hhh)(1)(A) of the Act specifies that a personalized prevention plan for an individual includes a health risk assessment (HRA) that meets the guidelines established by the Secretary and takes into account the results of a HRA. We are proposing to incorporate the use and results of an HRA as part of the provision of personalized prevention plan services during the AWV. The estimated impact of incorporating the HRA as part of the AWV is unknown for CY 2012. We are specifically seeking public comment on the following:

- The impact of use of the HRA on health professional practices.
- The burden on health professional practices of incorporating an HRA into subsequent AWVs, as well as the first AWV.
- The impact of the elements included in the definitions of first and subsequent AWVs.
- Modification of those AWV elements for which the Secretary has authority to determine appropriateness.

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

As discussed in section IV.F.1 of this proposed rule, we are proposing several different reporting options for eligible professionals who wish to participate in the 2012 Physician Quality Reporting System. Although there may be some cost incurred by CMS for maintaining the Physician Quality Reporting System measures and their associated code sets, and for expanding an existing clinical data warehouse to accommodate the proposed registry-based reporting, EHR-Based reporting, and group practice reporting options for the 2012 Physician Quality Reporting System, we do not anticipate a significant cost impact on the Medicare program.

Participation in the CY 2012 Physician Quality Reporting System by individual eligible professionals and group practices is voluntary and individual eligible professionals and group practices may have different processes for integrating the collection of the Physician Quality Reporting System measures into their practice's work flows. Given this variability and the multiple reporting options that we provide, it is difficult to definitively estimate the impact of the Physician Quality Reporting System on providers. Furthermore, we believe that costs for eligible professionals who are participating in the Physician Quality Reporting System for the first time in 2012 would be considerably higher than the cost for eligible professionals who participated in the Physician Quality Reporting System in prior years. Some preparatory steps are needed to begin participating in the Physician Quality Reporting System. To the extent that we are not proposing to retire the measures that an eligible professional has reported in a prior year and there are no changes to the measure's specifications from a prior year, such preparatory steps would not need to be repeated in subsequent years. In addition, for many eligible professionals, the cost of participating in the Physician Quality Reporting System is offset by the incentive payment received.

With respect to the potential incentive payments that would be made to satisfactory reporters under the 2012 Physician Quality Reporting System, we estimate this amount for individual eligible professionals would be approximately $60 million. This estimate is derived from looking at our 2009 incentive payment of approximately $235 million and then accounting for the fact that the 2009 incentive payment was 2.0 percent of an eligible professional's total estimated Medicare Part B PFS allowed charges for all such covered professional services furnished by the eligible professional during the 2009 reporting period. For 2012, the incentive payment is 0.5 percent of an eligible professional's total estimated Medicare Part B PFS allowed charges for all covered professional services furnished by an eligible professional during the 2012 reporting period. Although we expect that the lower incentive payment percentage for 2012 would reduce the total outlay by approximately one-fourth, we also expect more eligible professionals to participate in the 2012 Physician Quality Reporting System because there we are proposing more methods of data submission, additional alternative reporting methods, and because CMS seeks to align the Physician Quality Reporting System with the EHR Incentive Program. We also believe that some eligible professionals would

qualify for the additional 0.5 percent incentive authorized under section 1848(m)(7) of the Act (''Additional Incentive Payment'').

One factor that influences the cost to individual eligible professionals is the time and effort associated it would take individual eligible professionals to identify applicable proposed Physician Quality Reporting System quality measures and reviewing and selecting a reporting option. This burden would vary with each individual eligible professional by the number of applicable measures, the eligible professional's understanding of the Physician Quality Reporting System, experience with Physician Quality Reporting System participation, and the proposed method(s) selected by the eligible professional for reporting of the proposed measures, and incorporating the reporting of the proposed measures into the office work flows. Information obtained from the Physician Voluntary Reporting Program (PVRP), which was a predecessor to the Physician Quality Reporting System and was the first step for the reporting of physician quality of care through certain quality metrics, indicated an average labor cost per practice of approximately $50 per hour in 2006. To account for salary increases over time, we will use an average practice labor cost of $60 per hour for our estimates, based on an assumption of an average annual increase of approximately 3 percent. Therefore, assuming that it takes an individual eligible professional approximately 5 hours to review the Physician Quality Reporting System quality measures, review the various reporting options, select the most appropriate reporting option, identify the applicable measures for which they can report the necessary information, and incorporate reporting of the selected measures into their office work flows, we estimate that the cost to eligible professionals associated with preparing to report Physician Quality Reporting System quality measures would be approximately $300 per individual eligible professional ($60 per hour × 5 hours).

Another factor that influences the cost to individual eligible professionals is how they choose to report the Physician Quality Reporting System measures (that is, whether they select the claims-based, registry-based or EHR-Based reporting mechanism we are proposing). For the proposed claims-based reporting mechanism, estimates from the PVRP indicate the time needed to perform all the steps necessary to report quality data codes (QDCs) for 1 measure on a claim ranges from 15 seconds (0.25 minutes) to 12 minutes for complicated cases or measures. 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 Physician Quality Reporting System 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 impact analysis we will assume that an eligible professional will would need to report each selected measure for 6 reporting instances, or 6 cases. Assuming that an eligible professional, on average, would report 3 measures since a majority of eligible professionals participate in the Physician Quality Reporting System by reporting individual measures via claims or registry and that an eligible professional reports on an average of 6 reporting instances per measure, we estimate that the cost to an individual eligible professional associated with the proposed claims-based reporting option of Physician Quality Reporting System measures would range from approximately $4.50 (0.25 minutes per reporting instance × 6 reporting instances per measure × 3 measures × $60 per hour) to $216.00 (12 minutes per reporting instance × 6 reporting instances per measure × 3 measures × $60 per hour). If an eligible professional satisfactorily reports, these costs would more than likely be negated by the incentive earned. For the 2009 Physician Quality Reporting System, which had a 2.0 percent incentive, the mean incentive amount was close to $2,000 for an individual eligible professional. For the proposed registry-based reporting option, individual eligible professionals would generally incur a cost to submit data to registries. We estimate that fees for using a qualified registry would range from no charge, or a nominal charge, for an individual eligible professional to use a registry to several thousand dollars, with a majority of registries charging fees ranging from $500 to $1,000. However, our impact analysis is limited to the incremental costs associated with Physician Quality Reporting System reporting, which we believe are minimal. We believe that many eligible professionals who would select the proposed registry-based reporting option would already be utilizing the registry for other purposes and would not need to report additional data to the registry specifically for Physician Quality Reporting System. The registries also often provide the eligible professional services above and beyond what is required for Physician Quality Reporting System.

For the proposed EHR-Based reporting option, an individual eligible professional generally would incur a cost associated with purchasing an EHR product. Although we do not believe that the majority of eligible professionals would purchase an EHR solely for the purpose of participating in Physician Quality Reporting System, cost estimates for EHR adoption by eligible professionals from the EHR Incentive Program final rule (75 FR 44549) show that an individual eligible professional who chooses to do so would have to spend anywhere from $25,000 to $54,000 to purchase and implement an EHR and up to $18,000 annually for ongoing maintenance.

Although we believe that the majority of eligible professionals attempting to qualify for the additional 0.5 percent incentive payment authorized by section 1848(m)(7) of the Act would be those who are already required by their Boards to participate in a Maintenance of Certification Program, individual eligible professionals who wish to qualify for the additional 0.5 percent incentive payment and are not currently participating in a Maintenance of Certification Program would also have to incur a cost for participating in a Maintenance of Certification Program. The manner in which fees are charged for participating in a Maintenance of Certification Program vary by specialty. Some Boards charge a single fee for participation in the full cycle of Maintenance of Certification Program. Such fees appear to range anywhere from over $1,100 to nearly $1,800 per cycle. Some Boards have annual fees that are paid by their diplomates. On average, ABMS diplomates pay approximately $200.00 per year for participating in Maintenance of Certification Program. Some Boards have an additional fee for the Maintenance of Certification Program Part III secure examination, but most Boards do not have additional charges for participation in the Part IV practice/quality improvement activities.

With respect to the proposed requirements for group practices to be treated as satisfactorily submitting quality measures data for the CY 2012 Physician Quality Reporting System discussed in section IV.F.1 of this proposed rule, group practices interested in participating in the CY 2012 Physician Quality Reporting System through the proposed group practice reporting option (GPRO) may also incur a cost. However, for groups that satisfactorily report for the proposed 2012 Physician Quality

Reporting System, we believe these costs would be completely offset if the group practice earns the incentive payment since the group practice would be eligible for an incentive payment equal to 0.5 percent of the entire group's total estimated Medicare Part B PFS allowed charges for covered professional services furnished by the group practice during the reporting period.

One factor in the cost to group practices would be the costs associated with the proposed self-nomination process. Similar to our estimates for staff involved with the proposed claims-based reporting option for individual eligible professionals, we also estimate that the group practice staff involved in the proposed group practice self-nomination process would have an an average labor cost of $60 per hour. Therefore, assuming 2 hours for a group practice to decide whether to participate as a group or have members of the practice participate individually and 4 hours for the self-nomination process, we estimate the total cost to a group practice associated with the group practice self-nomination process would be approximately $360 ($60 per hour × 6 hours per group practice).

For groups participating under the proposed GPRO process that are comprised of 25 or more eligible professionals, another factor in the cost to the group would be the time and effort associated with the group practice completing and submitting the proposed data collection tool. Based on the Physician Group Practice (PGP) demonstration's estimate that it takes approximately 79 hours for a group practice to complete the data collection tool, which uses the same data submission methods as those we have proposed, we estimate the cost associated with a physician group completing the data collection tool would be approximately $4,740 ($60 per hour × 79 hours per group practice).

In addition to costs incurred by individual eligible professionals and group practices, registries and EHR vendors may also incur some costs related to the proposals for the 2012 Physician Quality Reporting System. Registries interested in becoming ''qualified'' to submit on behalf of individual eligible professionals would also have to incur a cost associated with the vetting process, and with calculating quality measures results from the data submitted to the registry by its participants, and submitting the quality measures results, as well as numerator and denominator data on quality measures, to CMS on behalf of their participants. We estimate the registry self-nomination process will cost approximately $500 per registry ($50 per hour × 10 hours per registry). This cost estimate includes the cost of submitting the self-nomination letter to CMS and completing the proposed CMS vetting process. Our estimate of $50 per hour average labor cost for registries is based on the assumption that registry staff include IT professionals whose average hourly rates range from $36 to $84 per hour depending on experience, with an average rate of nearly $50 per hour for a mid-level programmer. We do not believe that there are any additional costs for registries associated with a registry calculating quality measures results from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants under the proposed program for 2012. We believe that the majority of registries already perform these functions for their participants.

An EHR vendor interested in having its product(s) be used by individual eligible professionals to submit the proposed Physician Quality Reporting System measures to CMS for 2012 would have to complete the proposed vetting process during 2012 and program its EHR product(s) to extract the clinical data that the eligible professional would need to submit to CMS for purposes of reporting the proposed 2012 quality measures in 2013 as well. We proposed that previously qualified vendors would need to only update their electronic measure specifications and data transmission schema during 2012 to incorporate any new EHR measures we proposed to maintain their qualification for the 2012 Physician Quality Reporting System. Therefore, for EHR vendors that were not previously qualified, we estimate the cost associated with completing the proposed self-nomination process, including the proposed vetting process with CMS officials, is estimated would be $500 ($50 per hour × 10 hours per EHR vendor). Our estimate of a $50 per hour average labor cost for EHR vendors is based on the assumption that vendor staff include IT professionals whose average hourly rates range from $36 to $84 per hour depending on experience, with an average rate of nearly $50 per hour for a mid-level programmer. We believe that the cost associated with the time and effort needed for an EHR vendor to review the proposed quality measures and other information and program the EHR product to enable individual eligible professionals to submit Physician Quality Reporting System proposed quality measures data to the CMS-designated clinical warehouse would be dependent on the EHR vendor's familiarity with the Physician Quality Reporting System, the vendor's system's capabilities, as well as the vendor's programming capabilities. Some vendors already have the necessary capabilities and for such vendors, we estimate the total cost would be approximately $2,000 ($50 per hour × 40 hours per vendor). However, given the variability in the capabilities of the vendors, we believe an estimate for those vendors with minimal experience would be approximately $10,000 per vendor ($50 per hour × 200 hours per EHR vendor).

TABLE 67—ESTIMATED COSTS TO PROFESSIONALS: PHYSICIAN QUALITY REPORTING

	Estimated hours	Estimated instances	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation.	5.0	1	N/A	$60	$300.
Individual EP: Claims Reporting	0.2	6	3	60	$216.
Individual EP: Registry Reporting	N/A	1	N/A	N/A	$500 to $1,000.
Individual EP: EHR Reporting	N/A	1	N/A	N/A	$25,000–$54,000 initial start-up.
					$18,000 annually for subsequent years.
Group Practice: Self-Nomination	6.0	1	N/A	60	$360.
Group Practice: Reporting	79	1	N/A	60	$4,740.

TABLE 68—ESTIMATED COSTS TO VENDORS: PHYSICIAN QUALITY REPORTING

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$50	$500
EHR: Self-Nomination	10	50	500
EHR: Programming	40–200	50	2,000–10,000

6. Incentives for Electronic Prescribing (eRx)—The Electronic Prescribing Incentive Program

Section IV.F.2. of this proposed rule describes the proposed Electronic Prescribing (eRx) Incentive Programs for CYs 2012 through 2014. To be considered a successful electronic prescriber in CYs 2012 through 2014, an individual eligible professional would need to meet the proposed requirements described in section IV.F.2. of this proposed rule.

We estimate that the cost impact of the proposed eRx Incentive Programs for CYs 2012 through 2014 on the Medicare program would be the cost incurred for maintaining the electronic prescribing measure and its associated code set, and for maintaining the existing clinical data warehouse to accommodate the proposed registry-based reporting and EHR-Based reporting options for the electronic prescribing measure. However, we do not believe that the proposed program for CYs 2012 through 2014 has a significant administrative cost impact on the Medicare program since much of this infrastructure has already been established for the eRx Incentive Program.

Individual eligible professionals and group practices may have different processes for integrating data collection on the electronic prescribing measure into their practices' work workflows. Given this variability and the multiple reporting options that we are proposing, it is difficult to accurately estimate the impact of the eRx Incentive Program for CYs 2012 through 2014 on providers. Furthermore, we believe that costs for eligible professionals who would participate in the eRx Incentive Program for the first time would be considerably higher than the cost for eligible professionals who participated in the eRx Incentive Program in prior years as there are preparatory steps that an eligible professional would need to take to begin participating in the program. In addition, for many eligible professionals (especially those who participated in the eRx Incentive Program in prior years), we believe the cost of participating in the eRx Incentive Program in 2012 or 2013 would be offset by the incentive payment received. As a result of the payment adjustment that begins in 2012 and continues until 2014, the cost of not participating in the eRx Incentive Program for CYs 2012 through 2014 could be higher than the cost of participating in the form of reduced Medicare payments as a result of the payment adjustment.

For the 2009 eRx Incentive Program, based on an incentive of 2.0 percent of eligible professionals' total estimated Medicare Part B allowed charges, approximately $148 million in total incentives were paid to eligible professionals with a mean incentive amount of approximately $3,000. Based on the aforementioned figures from the 2009 eRx Incentive Program, we estimate that the total incentive payments for individual eligible professionals for the 2012 eRx incentive would be approximately $74 million, taking into account that the incentive payment for 2012 would be 1.0 percent. Assuming no changes in the participation rates, we estimate that the total incentive payments for the 2013 eRx incentive would be approximately $37 million, taking into account that the incentive payment for 2013 would be 0.5 percent.

From 2009, 89,752 eligible professionals participated in the eRx Incentive Program. For purposes of the 2013 and 2014 payment adjustment, we anticipate that despite a decrease in the incentive payment amount from 2 percent in 2009 to 1 percent of total estimated Medicare Part B allowed charges for covered professional services in 2012 and 0.5 percent in 2013, more eligible professionals (and groups) will choose to participate in the eRx Incentive Program due to the 2013 and 2014 payment adjustments of 1.5 percent and 2.0 percent respectively on eligible professionals' totally estimated Medicare Part B allowed charges for not demonstrating that they are successful electronic prescribers. In order to become a successful electronic prescriber for purposes of the 2013 and 2014 payment adjustments, we are proposing to provide more opportunities to report on the electronic prescribing measure by concentrating only on the numerator of the measure. Furthermore, we are proposing to expand the reporting mechanisms for the 2013 and 2014 payment adjustments to include registry and EHR-Based reporting. Although we expect an increase in participation for purposes of the 2013 and 2014 payment adjustments, we believe that at least some of these anticipated increases would be offset by the additional significant hardship exemptions we have proposed for the 2013 and 2014 payment adjustments. As such, we expect that the participation level for the eRx Incentive Program will be approximately 90,000 eligible professionals, based on the level of participation in 2009 (which was the highest participation level for the eRx Incentive Program recorded as of yet).

Since we do not have participation results for the implementation of the eRx payment adjustment as the reporting period for the 2012 payment adjustment (the first of 3 such payment adjustments), we will base our estimates for the distribution of payment adjustment amounts on the incentives earned in the 2009 eRx Incentive Program. For the 2013 payment adjustment, taking into account that the payment adjustment would be 1.5 percent, we believe that the total payment adjustment amount would be $111 million. This is based off of the incentive amount distributed for the 2009 eRx Incentive Program. For the 2014 payment adjustment, taking into account that the payment adjustment would be 2.0 percent, we believe that the total payment adjustment amount would be $148 million. This is also based off of the incentive amount distributed for the 2009 eRx Incentive Program.

We propose that any eligible professional who wishes to participate in the eRx Incentive Program must have a qualified electronic prescribing system in order to participate. Therefore, a one-time potential cost to some individual eligible professionals would be the cost of purchasing and using an electronic prescribing system, which varies by the commercial software package selected, the level at which the professional currently employs information technology in his or her practice and the training needed. One study indicated that a midrange complete electronic medical record with electronic prescribing functionality costs $2,500 per license with an annual fee of $90 per license for quarterly updates of the

drug database after setup costs while standalone prescribing, messaging, and problem list system may cost $1,200 per physician per year after setup costs. Hardware costs and setup fees substantially add to the final cost of any software package. (Corley, S.T. (2003). ''Electronic prescribing: a review of costs and benefits.'' Topics in Health Information Management 24(1):29–38.). These are the estimates that we intend to use for our impact analysis.

Similar to the Physician Quality Reporting System, one factor in the cost to individual eligible professionals is the time and effort associated with individual eligible professionals reviewing the electronic prescribing measure to determine whether it is applicable to them, reviewing the available reporting options and selecting one, gathering the required information, and incorporating reporting of the measure into their office work flows. Since the eRx Incentive Program consists of only 1 quality measure, we estimate 2 hours as the amount of time needed for individual eligible professionals to prepare for participation in the eRx Incentive Program. Information obtained from the PVRP, which was a predecessor to the Physician Quality Reporting System and was the first step for the reporting of physician quality of care through certain quality metrics, indicated an average labor cost per practice of approximately $50 per hour. To account for salary increases over time, we will use an average practice labor cost of $60 per hour for our estimates, based on an assumption of an average annual increase of approximately 3 percent. At an average cost of approximately $60 per hour, we estimate the total preparation costs to individual eligible professionals to be approximately $120 ($60 per hour × 2 hours).

Another factor that influences the cost to individual eligible professionals is how they choose to report the electronic prescribing measure (that is, whether they select the claims-based, registry-based or EHR-Based reporting mechanism). For claims-based reporting, there would be a cost associated with reporting the appropriate QDC on the claims an individual eligible professional submits for payment. Based on the information from the PVRP described previously for the amount of time it takes a median practice to report one measure one time (1.75 minutes) and the requirement to report 25 electronic prescribing events during 2012, we estimate the annual estimated cost per individual eligible professional to report the electronic prescribing measure via claims-submission would be $43.75 (1.75 minutes per case × 1 measure × 25 cases per measure × $60 per hour). We believe that for most successful electronic prescribers who earn an incentive, these costs would be negated by the incentive payment received given that the median incentive for eligible professionals who qualified for a 2010 eRx incentive was around $1,600.

For eligible professionals who select the proposed registry-based reporting mechanism, we do not anticipate any additional cost for individual eligible professionals to report data to a registry, as individual eligible professionals opting for registry-based reporting are more than likely already reporting data to the registry. Little if any, additional data would need to be reported to the registry for purposes of participation in the eRx Incentive Program for CYs 2012 through 2014. Individual eligible professionals using registries for Physician Quality Reporting System would likely experience minimal, if any, increased costs charged by the registry to report this 1 additional measure.

For EHR-Based reporting, we propose that the eligible professional must extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. Once the EHR is programmed by the vendor to allow data submission to CMS, the cost to the individual eligible professional associated with the time and effort to submit data on the electronic prescribing measure should be minimal.

With respect to the proposed process for group practices to be treated as successful electronic prescribers for the 2012 and 2013 incentive and 2013 and 2014 payment adjustment discussed in section IV.F.2. of this proposed rule, group practices have the same proposed options as individual eligible professionals in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices have the option of reporting the measure through claims, a qualified registry, or a qualified EHR product). There are only 2 differences between the proposed requirements for an individual eligible professional and a group practice: (1) The fact that a group practice would have to self-nominate; and (2) the number of times a group practice would be required to report the electronic prescribing measure. Overall, there could be less cost associated with a practice participating in the eRx Incentive Program as a group rather than the individual members of the group separately participating. We do not believe that there are any additional costs associated with the group practice self-nomination process since we are limiting the group practices to those selected to participate in the 2012, 2013, and/or 2014 respective Physician Quality Reporting System GPRO. The practices only will need to indicate their desire to participate in the eRx GPRO at the time they self-nominate for the Physician Quality Reporting System GPRO.

The costs for a group practice reporting to an EHR or registry should be similar to the costs associated with registry and EHR reporting for an individual eligible professional, as the process is the same with the exception that more electronic prescribing events must be reported by the group. For similar reasons, the costs for a group practice reporting via claims should also be similar to the costs associated with claims-based reporting for an individual eligible professional. Therefore, we estimate that the costs for group practices who are selected to participate in the eRx Incentive Program for CYs 2012 through 2014 as a group would range from $3,349.61 (1.75 minutes per case × 1 measure × 625 cases per measure × $60 per hour) for groups comprised of 25–99 eligible professionals participating as an eRx GPRO to $4,375.00 (1.75 minutes per case × 2,500 cases per measure × $60 per hour) for the groups comprised of 100 or more eligible professionals participating as an eRx GPRO.

We believe that the costs to individual eligible professionals and group practices associated with avoiding the 2013 and 2014 payment adjustment would be similar to the costs of an eligible professional or group practice reporting the electronic prescribing measure for purposes of the 2012 and 2013 incentive. Specifically, we believe that the cost of reporting the electronic prescribing measure in one instance for purposes of the payment adjustment is identical to the cost of reporting the electronic prescribing measure for one instance on claims for purposes of the incentive payment. The only difference would be in the total costs for an individual eligible professional. Group practices would be required to report the electronic prescribing measure for the same number of electronic prescribing events for both the 2012 and 2013 incentives and the 2013 and 2014 payment adjustments. Individual eligible professionals, however, would be required to report the electronic prescribing measure for only 10 electronic prescribing events for purposes of the 2013 and 2014 payment adjustments as opposed to 25 electronic

prescribing events for purposes of the 2012 and 2013 incentives.

Based on our decision to consider only registries qualified to submit quality measures results and numerator and denominator data on quality measures to CMS on their participant's behalf for the 2012, 2013, and 2014 Physician Quality Reporting System to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for eRx Incentive Program for CYs 2012, 2013, and 2014 respectively, we do not estimate any cost to the registry associated with becoming a registry qualified to submit the electronic prescribing measure for CYs 2012 through 2014.

The cost for the registry would be the time and effort associated with the registry calculating results for the electronic prescribing measure from the data submitted to the registry by its participants and submitting the quality measures results and numerator and denominator data on the eRx quality measure to CMS on behalf of their participants. We believe such costs would be minimal as registries would already be required to perform these activities for Physician Quality Reporting System.

Likewise, based on our decision to consider only EHR products qualified for the Physician Quality Reporting System for CYs 2012, 2013, and 2014 to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for the eRx Incentive Program for CYs 2012, 2013, and 2014, there would be no need for EHR vendors to undergo a separate self-nomination process for the eRx Incentive Program. Therefore, there would be no additional cost associated with the self-nomination process.

The cost to the EHR vendor associated with the proposed EHR-Based reporting requirements of this reporting initiative is the time and effort associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the individual eligible professional needs to submit to CMS for reporting the electronic prescribing measure. Since we determined that only EHR products qualified for the Physician Quality Reporting System would be qualified for the eRx Incentive Program, and the eRx Incentive Program consists of only one measure, we believe that any burden associated with the EHR vendor to program its product(s) to enable individual eligible professionals to submit data on the electronic prescribing measure to the CMS-designated clinical data warehouse would be minimal.

7. Physician Compare Web Site

Section IV.G.2. of this proposed rule discusses the background of the Physician Compare Web site. As described in section IV.G.2. of this proposed rule, we propose to develop aspects of the Physician Compare Web site 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 would occur during CYs 2011 through 2012, would include the posting of the names of eligible professionals who are successful electronic prescribers under the 2009 eRx Incentive Program, as well as eligible professionals (EPs) who participate in the EHR Incentive Program.

We are proposing to include performance information with respect to the 2012 Physician Quality Reporting System GPRO measures. As reporting of physician performance rates on the Physician Compare Web site will be performed directly by us using the data that we collect under the 2012 Physician Quality Reporting System GPRO, we do not anticipate any notable impact on eligible professionals with respect to the posting of information on the Physician Compare Web site.

8. Medicare EHR Incentive Program

Section IV.H.2. of this proposed rule proposes changes to the EHR Incentive Program for EPs for the 2012 payment year. Aside from continuing the attestation method of reporting CQMs, we propose to allow the reporting of CQMs for purposes of demonstrating meaningful use through participation in the Physician Quality Reporting System—Medicare EHR Incentive Pilot via—(1) A Physician Quality Reporting System ''qualified'' EHR data submission vendor or (2) using an EP's certified EHR technology, which also must be a Physician Quality Reporting System ''qualified'' EHR.

We believe the impact associated with actually reporting CQMs would vary depending on how the EP chooses to do so. We believe that the number of EPs who choose to participate via attestation would largely be those who are not participating in both the EHR Incentive Program and Physician Quality Reporting System as this is the method of reporting most favorable to EPs not participating in the Physician Quality Reporting System. EPs participating in the Physician Quality Reporting System would be more likely to participate in the proposed pilot. Therefore, based on the previously mentioned assumptions, we do not believe there would be any additional impact on EPs specific to the EP's participation in the proposed pilot. All the steps necessary to participate in the proposed pilot would need to be performed to participate in the Physician Quality Reporting System.

9. Physician Feedback Program/Value Modifier Payment

The proposed changes to the Physician Feedback Program in section IV.I. of this proposed rule would not impact CY 2012 physician payments under the Physician Fee Schedule. However, we expect that our proposals to use the Physician Quality Reporting System 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 Physician Quality Reporting System in CY 2012. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the Physician Quality Reporting System to determine and understand how the value modifier could affect their payments.

10. Bundling of Payments for Services Provided to Outpatients Who Later Are Admitted as Inpatients: 3-Day Payment Window Policy and the Impact on Wholly Owned or Wholly Operated Physician Offices

Medicare traditionally collects ownership information obtained in the 855 A and 855 B enrollment forms completed upon a facility or a practitioner's Medicare enrollment. The 855 forms are self-selecting enrollment forms that may be updated as necessary. Although the enrollment forms do not specifically require information on whether a physician office is wholly owned or wholly operated by a hospital, we will use this information to aid us in identifying physician offices and clinics that might be wholly owned or operated by a hospital. While we believe that most hospital owned entities providing physician services will be considered part of the hospital and operating as hospital outpatient departments; there will be at least some hospital owned physician offices and clinics that will meet the definition of ''wholly-owned or wholly-operated'' and will be subject to the 3-day payment window policy. We are unable to accurately estimate and verify the number of wholly owned or wholly operated physician offices or clinics enrolled in Medicare and furnishing health services to Medicare beneficiaries that will be subject to the 3-day

payment window policy under the PFS because the 855 forms do not explicitly capture information on sole ownership or operation. We note that the application of the 3-day window policy is limited to only those outpatient services provided within the payment window to patients that are admitted to a hospital. The 3-day window policy would not apply to the majority of services provided by wholly-owned or wholly-operated physician offices. Furthermore, application of the 3-day window policy would be limited to only the practice expense component of the payment rate, and the professional component will be unchanged by the payment policy. For the CY 2012 PFS proposed rule, we are unable to estimate the impact of this proposed policy change. However, we note that if we were able to estimate a savings in Part B payments as a result of the application of the 3-day payment window, the program savings would be redistributed across all other services paid under the PFS in accordance with due to the PFS budget neutrality provisions.

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 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 Physician Quality Reporting System with its focus on measuring, submitting, and analyzing quality data will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

The regulatory provisions may affect beneficiary liability in some cases. Most changes in aggregate beneficiary liability due to a particular provision would be a function of the coinsurance (20 percent if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 65, the CY 2011 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $102.95, which means that in CY 2011 a beneficiary would be responsible for 20 percent of this amount, or $20.59. Based on this proposed rule, including the negative update, the CY 2012 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 65, is $73.57, which means that, in CY 2012, the beneficiary coinsurance for this service would be $14.71. Most policies discussed in this proposed rule that impact payment rates, such as the expansion of the MPPR to the professional component of imaging procedures, would similarly impact beneficiaries' coinsurance.

K. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 69, we have prepared an accounting statement showing the estimated expenditures associated with this proposed rule. This estimate includes the estimated CY 2012 incurred benefit impact associated with the estimated CY 2012 PFS conversion factor update based on the FY 2012 President's Budget baseline.

TABLE 69—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS

Category	Transfers
CY 2012 Annualized Monetized Transfers	Estimated decrease in expenditures of $20.2 billion for the PFS update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

L. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an Initial Regulatory Flexibility Act Analysis. The previous analysis, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

VIII. Addenda Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the Addenda referred to throughout the preamble of this proposed rule. Beginning with the CY 2012 PFS proposed rule, the PFS Addenda A, B, C, D, E, F, G, and H will no longer appear in the **Federal Register**. Instead, these Addenda, along with other supplemental documents, will be available through the Internet.

Readers who experience any problems accessing any of the Addenda that are posted on the CMS Web sites identified above should contact Erin Smith at (410) 786–4497.

The following PFS Addenda for CY 2012 PFS proposed rule are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2012 PFS proposed rule, refer to item CMS–1524–P.

Addendum A—Explanation and Use of Addendum B

Addendum B—Proposed Relative Value Units and Relations Information Used in Determining Medicare Payments for CY 2012

Addendum C—[Reserved]

Addendum D—Proposed CY 2012 Geographic Adjustment Factors (GAFs)

Addendum E—Proposed CY 2012 Geographic Practice Cost Indices (GPCIs) by States and Medicare Locality

Addendum F—Proposed CY 2012 Diagnostic Imaging Services Subject to the Multiple Procedure Payment Reduction

Addendum G—CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA

Addendum H—CY 2011 ''Always Therapy'' Services Subject to the Multiple Procedure Payment Reduction

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 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 of this proposed rule, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

2. Amend § 410.15(a) as follows:

A. Amending the definition of ''first annual wellness visit providing personalized prevention plan services'' by—

1. Revising the introductory text.
2. Redesignating paragraphs (i) through (ix) as paragraphs (ii) through (x).
3. Adding a new paragraph (i).
4. Revising newly redesignated paragraph (viii)(A).

B. Adding the definition of ''Health risk assessment''.

C. In the definition of ''subsequent annual wellness visit providing personalized prevention plan services''.

1. Revising the introductory text.
2. Redesignating paragraphs (i) through (vii) as paragraphs (ii) through (viii).
3. Adding a new paragraph (i).
4. Revising newly redesigned paragraphs (iii) and (vi)(B).

The revisions and additions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional, taking into account the results of a health risk assessment, as those terms are defined in this section:

(i) Review (and administration if needed) of a health risk assessment (as defined in this paragraph).

* * * * *

(viii) * * *

(A) A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in this section), health status, screening history, and age-appropriate preventive services covered by Medicare.

* * * * *

Health risk assessment means, for the purposes of this section, an evaluation tool that meets the following criteria:

(i) Collects self-reported information about the beneficiary.

(ii) Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.

(iii) Is appropriately tailored to and takes into account the communication needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs.

(iv) Takes no more than 20 minutes to complete.

(v) Addresses, at a minimum, the following topics:

(A) Demographic data, including but not limited to age, gender, race, and ethnicity.

(B) Self assessment of health status, frailty, and physical functioning.

(C) Psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, or fatigue.

(D) Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual practices, motor vehicle safety (seat belt use), and home safety.

(E) Activities of daily living (ADLs), including but not limited to, dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

(F) Instrumental activities of daily living (IADLs), including but not limited to, shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional, taking into account the results of a health risk assessment, as those terms are defined in this section:

(i) Review (and administration, if needed) of a health risk assessment (as defined in this section).

* * * * *

(iii) An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

* * * * *

(vi) * * *

(B) The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

* * * * *

3. Amend § 410.62 paragraph (b) by revising the paragraph heading to read as follows:

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

* * * * *

(b) Condition for coverage of outpatient speech-language pathology services furnished to certain inpatients of a hospital or a CAH or SNF.* * *

* * * * *

§ 410.78 [Amended]

4. In § 410.78 the introductory text of paragraph (b) is amended by removing the phrase ''and individual and group health and behavior assessment and intervention services furnished by an interactive telecommunications system if the following conditions are met:'' and adding in its place the phrase ''individual and group health and behavior assessment and intervention services, and smoking cessation services furnished by an interactive telecommunications system if the following conditions are met:''.

5. Amend § 410.140 by revising the definition of ''Deemed entity'' to read as follows:

§ 410.140 Definitions.

* * * * *

Deemed entity means an individual, physician, or entity accredited by an

approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

§ 410.141 [Amended]

6. Amend § 410.141 paragraph (b)(1) as follows:

A. Removing the term ''it'' and adding the phrase ''the training'' in its place.

B. Removing the cross-reference ''§ 410.32(a)'' and adding the cross-reference ''§ 410.32(a)(2)''.

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

Subpart B—Physicians and Other Practitioners

7. 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)).

8. Amend § 414.22 by revising paragraphs (b)(5)(i)(A) through (b)(5)(i)(C) to read as follows:

§ 414.22 Relative value units (RVUs).

* * * * *

(b) * * *

(5) * * *

(i) * * *

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated physician practice providing preadmission services under § 412.2(c)(5).

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

(C) *Outpatient therapy and CORF services.* Outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services) and CORF services billed under the physician fee schedule are paid using the nonfacility practice expense RVUs.

* * * * *

§ 414.65 [Amended]

9. In § 414.65 paragraph (a) is amended by removing the phrase ''and individual and group health and behavior assessment and intervention furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.'' and adding in its place the phrase ''individual and group health and behavior assessment and intervention, and smoking cessation services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.''

10. Amend § 414.90 as follows:

A. In paragraph (b), adding the definition of ''Certified electronic health record technology''.

B. In paragraph (b), revising the definitions of ''Group practice''.

C. Removing paragraph (c)(2).

D. Redesignating paragraph (c)(3) as (c)(2).

E. Revising paragraph (f)(1).

F. Removing paragraph (f)(2).

G. Redesignating paragraph (f)(3) as (f)(2).

H. Revising newly redesignated paragraph (f)(2) introductory text.

I. In newly redesignated paragraph (f)(2)(ii), removing the phrase ''behalf; or'' and adding in its place the phrase ''behalf.''

J. In newly redesignated paragraph (f)(2)(iii), removing the phrase ''containing real or dummy'' and adding in its place the phrase ''containing dummy''.

K. Revising paragraphs (g)(1), (g)(5), (i)(1) and (i)(2) introductory text.

The revisions and additions and read as follows:

§ 414.90 Physician Quality Reporting System.

* * * * *

(b) * * *

Certified electronic health record technology means an electronic health record vendor's product and version as described in 45 CFR 170.102.

Group practice means a physician group practice, as defined by a TIN, with 25 or more individual eligible professionals (or, as identified by NPIs) who have reassigned their billing rights to the TIN.

* * * * *

(f) * * *

(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) *Exceptions*—(A) *Program year 2011.* The reporting period for the program year 2011 is one of the following:

(*1*) The 12-month period from January 1 through December 31 of such program year; or

(*2*) The 6-month period from July 1 through December 31 of such program year.

(B) For 2012 and subsequent program years, the 6-month reporting period from July 1 through December 31 of such program year is 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:

(g) * * *

(1) Meets the participation requirements specified by CMS for the Physician Quality Reporting System group practice reporting option;

* * * * *

(5) 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.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a 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. For any program year in which 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 (f) of this section.

(ii) If, for the program year, the eligible professional participates in the Physician Quality Reporting System under a 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 qualify for a Physician Quality Reporting System incentive by meeting the requirements specified in

paragraph (f) of this section under that TIN.

* * * * *

(i) * * *

(1) To request an informal review, an eligible professional (or in the case of reporting under paragraph (g) of this section, group practices) 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) CMS will provide a written response within 90 days of the receipt of the original request.

* * * * *

11. Section 414.92 is amended as follows:

A. In paragraph (b), adding the definition of ''Certified electronic health record technology''.

B. In paragraph (b), revising paragraphs (ii) and (iii) of the definition of ''Group practice''.

C. Revising paragraph (c)(1).

D. In paragraph (c)(2), revise the paragraph heading.

E. Revising paragraph (c)(2)(ii).

F. Adding paragraph (c)(2)(iii).

G. In paragraph (d)(1), removing the phrase ''For purposes of this paragraph in 2011,'' is removed and adding in its place the phrase ''For purposes of this paragraph,''.

H. In paragraph (d)(2), removing the phrase ''For program year 2011,'' and adding in its place the phrase ''For the 2012 and 2013 incentive payments,''

I. Redesignating paragraph (f) as (g).

J. Adding a new paragraph (f).

§ 414.92 Electronic Prescribing Incentive Program.

* * * * *

(b) * * *

Certified electronic health record technology means an electronic health record vendor's product and version as described in 45 CFR 170.102.

Group practice * * *

(ii) In a Medicare-approved demonstration project or other Medicare program, under which Physician Quality Reporting System requirements and incentives have been incorporated; and

(iii) Has indicated its desire to participate in the electronic prescribing group practice reporting option.

* * * * *

(c) * * *

(1) *Incentive payments.* Subject to paragraph (c)(3) of this section, with respect to covered professional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber 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 (e) 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 electronic prescribing percent (as specified in paragraph (c)(1)(ii) of this section) of the total estimated allowed part B charges for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (e) of this section, by the group practice) during the applicable reporting period.

(2) Payment adjustment.* * * (ii) *Significant hardship exception.* CMS may, on a case-by-case basis, exempt an eligible professional (or in the case of a group practice under paragraph (e) of this section, a group practice) from the application of the payment adjustment under paragraph (c)(2) of this section if, CMS determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. Eligible professionals (or, in the case of a group practice under paragraph (e) of this section, a group practice) may request consideration for a significant hardship exemption from the 2013 and 2014 payment adjustments if one of the following circumstances apply:

(A) The eligible professional or group practice is located in a rural area without high speed internet access.

(B) The eligible professional or group practice is located in an area without sufficient available pharmacies for electronic prescribing.

(C) The eligible professional or group practice is unable to electronically prescribe due to local, State, or Federal law or regulation.

(D) 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.

(iii) Exemptions to the payment adjustment. An eligible professional (or in the case of a group practice under paragraph (b) of this section, a group practice) is exempt from the application of the payment adjustment under paragraph (c)(2) of this section if one of the following applies:

(A) The eligible professional is not an MD, DO, podiatrist, nurse practitioner, or physician assistant.

(B) The eligible professional does not have at least 100 cases containing an encounter code that falls within the denominator of the electronic prescribing measure for dates of service during the 6-month reporting period specified in paragraph (f)(1) of this section.

* * * * *

(f) *Requirements for individual eligible professionals and group practices for the payment adjustment.* In order to be considered a successful electronic prescriber for the electronic prescribing payment adjustment, an individual eligible professional (or, in the case of a group practice under paragraph (b) of this section, a group practice), as identified by a unique TIN/NPI combination, must meet the criteria for being a successful electronic prescriber specified by CMS, in the form and manner specified in paragraph (f)(2) of this section, and during the reporting period specified in paragraph (f)(1) of this section.

(1) *Reporting periods.* (i) For purposes of this paragraph, the reporting period for the 2013 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2011 through December 31, 2011.

(B) The 6-month period from January 1, 2012 through June 30, 2012.

(ii) For purposes of this paragraph, the reporting period for the 2014 payment adjustment is either of the following:

(A) The 12-month period from January 1, 2012 through December 31, 2012.

(B) The 6-month period from January 1, 2013 through June 30, 2013.

(2) *Reporting mechanisms.* For program years 2012 through 2014, an eligible professional (or, in the case of a group practice under paragraph (e) of this section, a group practice) who wishes to participate in the Electronic Prescribing Incentive Program must report information on the electronic prescribing measure identified by CMS to one of the following:

(i) CMS, by no later than 2 months after the end of the applicable 12-month reporting period or by no later than 1 month after the end of the applicable 6-month reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section.

(ii) A qualified registry (as defined 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 qualified registry submits information, as required by CMS, for covered professional services furnished by the eligible professional during the reporting period specified in paragraph (f)(1) of this section to CMS on the eligible professional's behalf.

(iii) CMS by extracting clinical data using a secure data submission method, as required by CMS, from a qualified electronic health record 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 reporting period specified in paragraph (f)(1) of this section. Prior to actual data submission for a given program year and by a date specified by CMS, the eligible professional must submit a test file containing dummy clinical quality data extracted from the qualified electronic health record product selected by the eligible professional using a secure data submission method, as required by CMS.

* * * * *

Subpart J—Submission of Manufacturer's Average Sales Price Data

12. Section 414.802 is amended by revising the first sentence of the definition of ''unit'' to read as follows:

§ 414.802 Definitions.

* * * * *

Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by an NDC varies.

* * *

* * * * *

13. Section 414.904 is amended by revising paragraph (d)(3) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (d)(3)(iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next ASP payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the ASP has exceeded the AMP by the applicable threshold percentage, and will remain in effect for one quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when—

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met; and

(B) 103 percent of the AMP is less than the 106 percent of the ASP for the quarter in which the substitution would be applied.

(iii) The applicable percentage threshold for AMP comparisons for CYs 2005 through 2011 is 5 percent. For CY 2012, the applicable percentage threshold for ASP comparisons is reached when—

(A) The ASP for the billing code has exceeded the AMP for the billing code by 5 percent or more in two consecutive quarters, or three of the last 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 NDCs used for the average sales price for the billing code.

(iv) The applicable percentage threshold for WAMP comparisons for CYs 2005 through 2012 is 5 percent.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

14. 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).

Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers

§ 415.130 [Amended]

15. In § 415.130, paragraphs (d)(1) and (d)(2) are amended by removing the date ''December 31, 2010'' and adding the date ''December 31, 2011'' in its place.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

16. The authority 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).

17. Amend § 495.8 as follows:

A. In pargraph (a)(2)(ii), removing the phrase ''selected by CMS electronically to CMS (or in the case of Medicaid EPs, the States) in the manner specified by CMS (or in the case of Medicaid EPs, the States).'' and adding in its place the phrase ''selected by CMS to CMS (or in the case of Medicaid EPs, the States) in the form and manner specified by CMS (or in the case of Medicaid EPs, the States).''

B. Adding a new 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—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.* In order to satisfy the clinical quality measure reporting objective in § 495.6(d)(10), 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.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 24, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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