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Part II—Continued

Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, et al.

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

TABLE 53: Measures Proposed for Inclusion in the Physician Quality Reporting System Measure Beginning in 2014 that are Not Finalized to be Included in the Physician Quality Reporting System Measure Beginning in 2014

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/ N/A	Patient Safety	**Atopic Dermatitis: Overuse: Role of Antihistamine:** Percentage of patients aged 25 years or younger seen at one or more visits within a 12-month period with a diagnosis of atopic dermatitis, who did not have a diagnosis of allergic rhinitis or urticaria, who were prescribed oral nonsedating antihistamines One commenter supported the inclusion of this measure as it would gather data on the "percentage of patients aged 25 years or younger seen at one or more visits within a 12-month period with a diagnosis of atopic dermatitis, who did not have a diagnosis of allergic rhinitis or urticaria, who were prescribed oral nonsedating antihistamines." Another commenter did not support inclusion of this measure in the PQRS program. We agree with the latter commenter that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS.	AMA-PCPI		X				

N/A/ N/A	Effective Clinical Care	**Neurosurgery: Initial Visit:** The percentage of patients aged 18 through 80 years with a diagnosis of a neurosurgical procedure or pathology who had function assessed during the initial visit to the clinician for the episode of the condition The measure owner withdrew support of this measure and therefore, we are not finalizing it for inclusion in 2014 PQRS.	AANS/CNS		X				
0372/N/A	Patient Safety	**VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis:** This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer) Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting program but were concerned about the ability to implement this measure in PQRS. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. However, CMS is deferring the incorporation of the IQR measures until 2015 due to operational issues with implementation. As such, we are not finalizing this measure for inclusion in 2014 PQRS.	The Joint Commission		X				IQR

N/A/N/A	Patient Safety	**VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol:** This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol. Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting program but were concerned about the ability to implement this measure in PQRS. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. However, CMS is deferring the incorporation of the IQR measures until 2015 due to operational issues with implementation. As such, we are not finalizing this measure for inclusion in 2014 PQRS.	The Joint Commission		X				IQR
0495/N/A	Communication and Care Coordination	**ED-1a: Median Time from ED Arrival to ED Departure for Admitted ED Patients - Overall Rate:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting program but were concerned about the ability to implement this measure in PQRS. CMS appreciates commenter's support of this measure but is deferring the incorporation of the IQR measures until 2015 due to operational issues with implementation. As such, we are not finalizing this measure for inclusion in 2014 PQRS.	CMS		X				IQR

1659/N/A	Community/ Population Health	**IMM-1c: Pneumococcal Immunization (PPV23) – High Risk Populations (Age 5 through 64 years):** This prevention measure addresses acute care hospitalized inpatients 65 years of age and older (IMM-1b) AND inpatients aged between 5 and 64 years (IMM-1c) who are considered high risk and were screened for receipt of pneumococcal vaccine and were vaccinated prior to discharge if indicated. The numerator captures two activities; screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to pneumococcal vaccine, patients who were offered and declined pneumococcal vaccine and patients who received pneumococcal vaccine anytime in the past are captured as numerator events Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Other commenters did not support inclusion of this measure in the PQRS program due to its suspension from the IQR program and difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.	CMS		X				IQR

0147/N/A	Patient Safety	**PN-6: Initial Antibiotic Selection for CAP in Immunocompetent** **Patient:** Immunocompetent patients with Community-Acquired Pneumonia who receive an initial antibiotic regimen during the first 24 hours that is consistent with current guidelines Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Other commenters did not support inclusion of this measure due to difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.	CMS		X				IQR
0495/N/A	Communication and Care Coordination	**ED-1d: Median Time from ED Arrival to ED Departure for Admitted Patients - Psychiatric/Mental Health Patients:** Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department One commenter appreciates CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Several commenters did not support inclusion of this measure due to difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.	CMS		X				IQR

0166/N/A	Communication and Care Coordination	**HCAHPS: Hospital Consumer Assessment of Healthcare Providers and Systems Survey:** 27-items survey instrument with 7 domain-level composites including: communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness and quiet of the hospital environment, and discharge information One commenter appreciates CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Several commenters did not support inclusion of this measure due to difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.	CMS		X				IQR
N/A/N/A	Effective Clinical Care	**Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Iatrogenic Injury to Adjacent Organ/Structure:** Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect The measure owner withdrew support of this measure and therefore, we are not finalizing it for inclusion in 2014 PQRS.	ACS					X	

N/A/N/A	Effective Clinical Care	**Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Iatrogenic Injury to Adjacent Organ/Structure:** Percentage of patients age 65 and older who had an iatrogenic injury documented in the operative note, postoperative note, or progress note. Iatrogenic injury is an unplanned laceration, puncture, transection or cautery injury to an adjacent structure (e.g., sphincters, vasculature, nerve, other) that occurs during the index procedure, whether recognized at the time of surgery or post-operatively. Synonyms for the injury could include: hole, wound, perforation, tear, injury, laceration, cautery injury, damage, disruption, or defect The measure owner withdrew support of this measure and therefore, we are not finalizing it for inclusion in 2014 PQRS.	ACS					X	

¥ Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ based on reporting mechanism within PQRS. Additionally, there may be tittle and description variations for the same measure across other quality reporting programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

In Table 54, we specify the measures we proposed to remove from reporting under the PQRS and whether, based on the comments received, we are finalizing our proposal to remove these measures from reporting under the PQRS in 2014. Please note that the rationale we have for finalizing removal of each measure is specified after the measure title and description.

TABLE 54: Measures To Be Removed from Reporting in the Physician Quality Reporting System in 2014

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0061/ 3	Effective Clinical Care	**Diabetes Mellitus: High Blood Pressure Control:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) **Rationale:** Measure deletion due to direction of eliminating duplicative measures within PQRS. One commenter supported the removal of this measure, while another commenter cautioned against removal of this measure until new guidelines are established for development of a comprehensive blood pressure control measure that is clinically relevant for Ischemic Vascular Disease and Diabetes. A third commenter cautioned against the removal due to the importance of blood pressure control for patients with diabetes. Additionally, commenters were concerned with the removal of this measure as it impacts the number of measures available to eligible professionals.	NCQA	X	X	X		X	MU1

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		We appreciate the comments and understand the concerns. Due to our desire to move away from claims-based reporting, we are not finalizing this measure for inclusion in 2014 PQRS.							
N/A/ 86	Effective Clinical Care	**Hepatitis C: Antiviral Treatment Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters feedback and are not finalizing this measure for reporting under PQRS.	AMA-PCPI	X	X			X	
N/A/ 89	Effective Clinical Care	**Hepatitis C: Counseling Regarding Risk of Alcohol Consumption:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12-months	AMA-PCPI	X	X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: Measure lost NQF Endorsement/Measure Owner Support. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters feedback and are not finalizing this measure for reporting under PQRS.							
N/A/ 90	Effective Clinical Care	**Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy:** Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters feedback and	AMA-PCPI	X	X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		are not finalizing this measure for reporting under PQRS.							
N/A/ 161	Effective Clinical Care	**HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy:** Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm^3 or who have a history of an AIDS-defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. CMS solicited but received no comments on this measure. Therefore, for the reasons we stated in the proposed rule, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.	AMA-PCPI/NCQA		X			X	
N/A/ 162	Effective Clinical Care	**HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who	AMA-PCPI/NCQA		X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. CMS solicited but received no comments on this measure. We are finalizing our proposal to retire this measure from PQRS beginning in 2014.							
N/A/ 184	Community/Population Health	**Hepatitis C: Hepatitis B Vaccination in Patients with HCV:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. Two commenters did not agree with the removal of this measure and requested that	AMA- PCPI	X	X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		CMS reconsider, stating this measure addresses an important aspect of care. Additionally, this measure is paired with PQRS 183 which was proposed for continued inclusion for the 2014 program year. We appreciate the commenter's feedback, but, based on the rationale provided above, we are not retaining this measure for reporting under PQRS.							
N/A/ 188	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear:** Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a congenital or traumatic deformity of the ear (internal or external) **Rationale:** Measure deletion due to low utilization and lack of clinical relevance for the Medicare population. CMS solicited but received no comments on this measure. Therefore, for the reasons provided above, we are finalizing our	AQC	X	X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		proposal to retire this measure from PQRS beginning in 2014.							
N/A/ 200	Effective Clinical Care	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation:** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy **Rationale:** Measure lost NQF Endorsement/Measure Owner Support. One commenter did not support the retirement of this measure. Several commenters supported the removal of this measure as it has been retired from the medical professional society's measure set, while one commenter did not support the retirement, stating it is pertinent to the field of electrophysiology. We appreciate the commenters feedback and for the reasons identified, are not finalizing this measure for reporting under PQRS	AMA-PCPI/ACCF/AHA			X			MU1
0073/ 201	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Blood Pressure Management:** Percentage of patients aged 18 to 75 years with Ischemic Vascular Disease (IVD) who had most recent	NCQA	X	X	X		X	MU1

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		blood pressure in control (less than 140/90 mmHg) **Rationale:** Measure deletion due to direction of eliminating duplicative measures within PQRS. One commenter supported the removal of this measure. Another commenter cautioned against removal of this measure until new guidelines are established for development of a comprehensive blood pressure control measure that is clinically relevant for Ischemic Vascular Disease and Diabetes. Additionally, commenters were concerned with the removal of this measure as it impacts the number of measures available to eligible professionals. We appreciate the comments and understand the concerns. Due to our desire to move away from claims-based reporting, we are not finalizing this measure for inclusion in 2014 PQRS.							
0410/208	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months	AMA-PCPI/NCQA		X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: Measure owner combined NQF 0410 with NQF 0409. CMS solicited but received no comments on this measure. Therefore, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.							
0445/ 209	Effective Clinical Care	**Functional Communication Measure - Spoken Language Comprehension:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Comprehension Functional Communication Measure **Rationale:** Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but for the reason above we are not retaining this measure for reporting under PQRS.	ASHA		X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0449/ 210	Effective Clinical Care	**Functional Communication Measure – Attention:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Attention Functional Communication Measure **Rationale:** Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but we are not retaining this measure for reporting under PQRS for the reason above.	ASHA		X				
0448/ 211	Effective Clinical Care	**Functional Communication Measure – Memory:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Memory Functional Communication Measure **Rationale:** Measure lost Measure Owner support.	ASHA		X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.							
0447/ 212	Effective Clinical Care	**Functional Communication Measure - Motor Speech:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Motor Speech Functional Communication Measure **Rationale:** Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.	ASHA		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0446/ 213	Effective Clinical Care	**Functional Communication Measure – Reading:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Reading Functional Communication Measure **Rationale:** Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.	ASHA		X				
0444/ 214	Effective Clinical Care	**Functional Communication Measure - Spoken Language Expression:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language Expression Functional Communication Measure	ASHA		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.							
0442/ 215	Effective Clinical Care	**Functional Communication Measure – Writing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Writing Functional Communication Measure **Rationale:** Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons	ASHA		X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		stated above, we are not retaining this measure for reporting under PQRS.							
0443/ 216	Effective Clinical Care	**Functional Communication Measure – Swallowing:** Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Swallowing Functional Communication Measure **Rationale:** Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.	ASHA		X				
0013/ 237	Effective Clinical Care	**Hypertension (HTN): Blood Pressure Measurement:** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded	AMA-PCPI			X			

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: Deletion due to MU2 alignment. Several commenters supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters' feedback and are not finalizing this measure for reporting under PQRS.							
N/A/ 244	Effective Clinical Care	**Hypertension: Blood Pressure Management:** Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more anti-hypertensive medications during the most recent office visit **Rationale:** Measure deletion due to direction of eliminating duplicative measures within PQRS. Two commenters believed this measure addresses important aspects of care while another is concerned its impact on the number of measures available to eligible professionals.	AMA-PCPI/ACCF/AHA		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		We appreciate the comment and understand the concerns. Due to our desire to move away from claims-based reporting, we are removing this measure from the PQRS measure set.							
0503/252	Effective Clinical Care	**Anticoagulation for Acute Pulmonary Embolus Patients:** Anticoagulation ordered for patients who have been discharged from the emergency department (ED) with a diagnosis of acute pulmonary embolus **Rationale:** Measure lost Measure Owner support. Two commenters requested that CMS retain this measure although it has lost measure owner support and NQF endorsement. CMS appreciates the commenters' desire to retain this measure in the PQRS program and encourages them to re-tool the measure as needed and submit during the annual Call for Measures for possible future inclusion.	ACEP	X	X				
N/A/ 256	Communication and Care Coordination	**Surveillance after Endovascular Abdominal Aortic Aneurysm Repair (EVAR):** Percentage of patients 18 years of age or older undergoing endovascular abdominal aortic aneurysm repair (EVAR)	SVS		X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		who have at least one follow-up imaging study after 3 months and within 15 months of EVAR placement that documents aneurysm sac diameter and endoleak status **Rationale:** Measure lost Measure Owner support. CMS solicited but received no comments on this measure. Therefore, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.							
0012/ 306	Community/Population Health	**Prenatal Care: Screening for Human Immunodeficiency Virus (HIV):** Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit **Rationale:** Deletion due to MU2 alignment. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenter's feedback and are not finalizing this measure for reporting under PQRS.	AMA-PCPI			X			MU1

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0014/ 307	Patient Safety	**Prenatal Care: Anti-D Immune Globulin:** Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation **Rationale:** Deletion due to MU2 alignment. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenter's feedback and are not finalizing this measure for reporting under PQRS.	AMA-PCPI			X			MU1
0027/ 308	Community/Population Health	**Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies:** Percentage of patients aged 18 years and older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation	NCQA			X			MU1

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		medications, methods or strategies **Rationale:** Deletion due to MU2 alignment. One commenter did not support the removal of this measure, stating it is an important measure in attempting to reduce tobacco usage. Another commenter was concerned tobacco cessation strategies would not be captured in existing smoking measures. We respectfully disagree and are therefore not finalizing this measure for inclusion in 2014 PQRS. We believe the tobacco cessation finalized in the PQRS measure set suffice to capture cessation consultation.								
0575/ 313	Effective Clinical Care	**Diabetes Mellitus: Hemoglobin A1c Control (< 8%):** The percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 or type 2) who had HbA1c < 8% **Rationale:** Deletion due to MU2 alignment. One commenter was concerned with the removal of this measure as it drives better quality compared to PQRS measure #1 and it	NCQA			X			

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		has the potential to contribute to better outcomes for patients with diabetes. Another commenter requested the measure not be retired as it provides different clinical information than PQRS measure #1 and that alignment with other programs is not an adequate reason for removal. We appreciate the commenters' feedback but respectfully disagree. It is our intention to align the measures available for EHR-based reporting under PQRS with the measures available for reporting under the Medicare EHR Incentive Program. Since this measure is not available for reporting under the EHR Incentive Program, we do not believe it is appropriate to include in the final PQRS measure set and are therefore not finalizing for inclusion in 2014 PQRS.							
0493/ 321	Communication and Care Coordination	**Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality:** Participation in a systematic qualified clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry. b. Data elements are applicable to consensus	OFMQ	X	X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		endorsed quality measures. c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or state-wide registry is encouraged for this measure. f. Registry may provide feedback directly to the provider's local registry if one exists. **Rationale:** Due we believe participation in a clinical data registry is best captured under the new qualified clinical data registry option, CMS no longer believes this measure is necessary to report and is therefore proposing to remove this measure. We received several comments opposing the removal of this measure due to the							

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		implementation of Qualified Clinical Data Registries, stating they believe it is premature and that the measure is an important bridge to increased registry-based PQRS reporting. The commenters urged CMS to postpone the elimination of this measure until it has a better understanding of how many registries will be able to fulfill the new Qualified Clinical Data Registry option as proposed. We appreciate the commenters' feedback, but we are not retaining this measure for reporting under PQRS.							
N/A/N/A	Communication and Care Coordination	**Total Knee Replacement: Coordination of Post Discharge Care:** Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits **Rationale:** Measure Owner decision to remove this measure from Total Knee Replacement and replace with the measure: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy	AAHKS/AMA-PCPI					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		CMS solicited but received no comments on this measure. Therefore, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.							
N/A/N/A	Person and Caregiver-Centered Experience and Outcomes	**Chronic Wound Care: Patient Education Regarding Long-Term Compression Therapy:** Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy including interval replacement of compression stockings within the 12 month reporting period **Rationale:** This measure concept is routinely met in a clinical setting. CMS believes it would not indicate a true quality outcome. Two commenters felt this measure adds an important aspect of care related to the two chronic wound care measures currently in the PQRS program. CMS appreciates the commenters' feedback but as indicated in our rationale, do not believe it would indicate a true quality outcome. For this reason, we are not finalizing for inclusion in PQRS.	AMA-PCPI	X	X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/N/A	Effective Clinical Care	**Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-bearing Exercise Advice:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating regularly who received advice within 12 months to participate in weight-bearing exercise **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Effective Clinical Care	**Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters'	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Patient Safety	**Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Effective Clinical Care	**Osteoporosis: Dual-Emission X-ray Absorptiometry (DXA) Scan:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group.	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Effective Clinical Care	**Osteoporosis: Calcium Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group.	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Effective Clinical Care	**Osteoporosis: Vitamin D Intake Assessment and Counseling:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group.	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Effective Clinical Care	**Osteoporosis: Pharmacologic Therapy:** Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Blood Pressure at Goal:** Percentage of patients in the sample whose most recent blood pressure reading was at goal **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal:** Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines:** Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a three-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a three-month grace period) for patients with ≥ 2 risk factors for CHD (smoking, hypertension, low high density lipid (HDL), men ≥ 45 years, women ≥ 55 years, family history of premature CHD; HDL ≥ 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a three-month grace period) for patients with ≤ 1 risk factor for CHD)	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but, based on the rationale stated above, we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Diabetes Documentation or Screen Test:** Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the removal of this measure because they believe it has potential to contribute to better outcomes for patients with diabetes. Another commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Counseling for Diet and Physical Activity:** Percentage of patients who received dietary and physical activity counseling	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI):** Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented **Rationale:** This measures group was deleted due to the amount of measures that had	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Appropriate Use of Aspirin or Other Antiplatelet/Anticoagulant Therapy:** Percentage of patients in the sample who are: 1) taking aspirin or other anticoagulant/antiplatelet therapy, or 2) under age 30, or 3) age 30 or older and who are documented to be at low risk. Low-risk patients include those who are documented with no prior coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD,	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus) and whose ten-year risk of developing CHD is < 10% **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	**Preventive Cardiology Composite: Smoking Status and Cessation Support:** Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		documented to have received smoking cessation counseling during the reporting period **Rationale:** This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							

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

b. PQRS Measures Groups

Section 414.90(b) defines a measures group as ''a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.''

In the CY 2014 PFS proposed rule, we proposed (78 FR 43448) to modify the minimum amount of measures that may be included in a PQRS measures group from four to six (78 FR 43448). Therefore, we proposed (78 FR 43448) to modify the definition of a measures group at § 414.90(b) to indicate that a measures group would consist of at least six measures. Consequently, we proposed (78 FR 43448) to add additional measures to each measures group that previously contained less than six measures (see Tables 31 through 56 at 78 FR 43449 through 43474). We solicited and received the following public comments on these proposals:

Comment: Several commenters did not support our proposal to modify the definition of a measures group at § 414.90(b) to indicate that a measures group would consist of at least six measures. Commenters believed that the proposal to increase the minimum number of measures in a measures group from four to six measures seemed arbitrary. Some of these commenters suggested that the measures CMS proposed to add to measures groups that previously contained less than six measures were not appropriate to these measures groups as they did not address the specific clinical topic or condition addressed in the measures groups.

Response: We understand the commenters' concerns regarding this proposal. Although we still plan to increase the minimum number of measures in a measures group in the future, we are not finalizing this proposal at this time. As such, we are not finalizing our proposals to add additional measures to measures groups that previously contained less than six measures. We will work with the measure developers and owners of these measures groups to appropriately add measures to measures groups that only contain four measures within the measures group.

In addition, we solicited and received the following comment on our specific proposed measures groups:

Comment: Chronic Kidney Disease Measures Group—One commenter supported all proposed measures in the Chronic Kidney Disease (CKD) measures group as they represent important aspects of care that can delay CKD progression and protect patients from adverse outcomes.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, the Chronic Kidney Disease (CKD) measures group will remain as it was finalized in 2013. Therefore, we are not including PQRS measure # 130: Documentation of Current Medications in the Medical Record and PQRS measure #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention, in the measures group as proposed.

Comment: Hypertension Measures Group—One commenter agrees with the Hypertension measures group but recommends replacing PQRS measure #300 Hypertension: Blood Pressure Control, with PQRS measure #236 Hypertension: Controlling High Blood Pressure, citing the reason of the expanded age range to 90 as inconsistent and creating confusion.

Response: We appreciate the commenters' feedback. However, we note that the age range of all of the measures within the Hypertension measures group is 18 through 90, and the existing measures have been examined to determine the ability to report and analyze the measures contained within the measures group as a whole, whereas the suggested PQRS measure has not been analyzed to determine the feasibility of reporting these measures together within a measures group.

Comment: Another commenter showed support for screening for chronic kidney disease in people with hypertension, but recommended replacing PQRS measure #297 Hypertension: Urine Protein Test and PQRS measure #298 Hypertension: Annual Serum Creatinine Test with a measure of documented eGFR and urine albumin-creatinine ration.

Response: CMS appreciates the commenters' suggestions, but as the suggested changes to the measures group have not been analyzed, nor were they included in the CY2014 PFS proposed rule, CMS is retaining the Hypertension measures group as it was finalized in the CY 2013 PFS final rule (77 FR 69272).

Comment: Cataracts Measures Group—Two commenters expressed concern with the proposed inclusion of Patient-Centered Surgical Risk Assessment and Communication in the Cataracts measures group, stating that this measure is not reportable for cataract surgeons.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the composition of the Cataracts measures group for 2014 as it was finalized in the CY 2013 PFS final rule (77 FR 69272). Therefore, we are not including PQRS measure # 130: Documentation of Current Medications in the Medical Record, PQRS measure #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention, and Patient-Centered Surgical Risk Assessment and Communication in the measures group as proposed.

Comment: Sleep Apnea Measures Group—Several commenters support the Sleep Apnea measures group. There was however, concern regarding the addition of PQRS measures #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up, # 130: Documentation of Current Medications in the Medical Record, and #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Sleep Apnea measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272). Therefore, we are not including PQRS measures #128, #130 and #226 in the measures group as proposed.

Comment: Dementia Measures Group—Several commenters expressed support for the retention of the Dementia measures group. One commenter urged that even though the measures are not NQF-endorsed they are retained for continued use in PQRS and other agency programs. One commenter did suggest the inclusion of three additional measures: (1) A measure that requires physicians to assess cognitive impairment using a standardized assessment tool; (2) a measure that requires documentation of a diagnosis in the medical record; and (3) the American Medical Association's (AMA) dementia performance measure on palliative care counseling and advance care planning.

Response: CMS appreciates the suggestions, however as previously stated, the existing measures have been examined to determine the ability to report and analyze the measures contained within the measures group as a whole, whereas the suggested measured have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Additionally, the suggested measures were not included

in the CY2014 PFS proposed rule. Therefore, CMS is retaining the Dementia measures group as it was finalized in the CY 2013 PFS final rule (77 FR 69272).

Comment: Perioperative Care Measures Group—Two commenters expressed concern with the proposed inclusion of the following measures in the Perioperative Care measures group: Patient-Centered Surgical Risk Assessment and Communication, PQRS measure # 130: Documentation of Current Medications in the Medical Record and PQRS measure #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Perioperative Care measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272). Therefore, we are not including Patient-Centered Surgical Risk Assessment and Communication, PQRS #130 and PQRS #226 in the measures group as proposed.

Comment: Ischemic Vascular Disease Measures Group—One commenter recommended not removing PQRS measure #201: Ischemic Vascular Disease (IVD): Blood Pressure Management from the IVD measures group without adding a measure focused on people with IVD. CMS appreciates the commenters' suggestions, but disagrees due to CMS' efforts to reduce duplicity in measures and the fact that this measure was not proposed for inclusion in the CY2014 PFS proposed rule. One commenter agreed with the CMS proposal to revise the Ischemic Vascular Disease measures group to include additional quality measures. CMS appreciates the commenters' support, but is not finalizing the proposal to increase the number of measures in a measures group from four to six.

Response: CMS is finalizing the Ischemic Vascular Disease measures group as it was finalized in CY 2013 PFS final rule (77 FR 69272), without PQRS measures #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up and #130: Documentation of Current Medications in the Medical Record.

Comment: Asthma Measures Group—One commenter noted that the Asthma measures group is an important measures group that is of interest to the pulmonary, critical care and sleep provider community. One commenter expressed concern with the inclusion of PQRS measures #110: Preventive Care and Screening: Influenza Immunization and #130: Documentation of Current Medications in the Medical Record, stating concern that is will create additional confusion for providers reporting on the measure group.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Asthma measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272) and not including PQRS #110 and PQRS #130 in the measures group as proposed.

Comment: Chronic Obstructive Pulmonary Disease (COPD) Measures Group—One commenter noted that the COPD measures group is an important measures group that is of interest to the pulmonary, critical care and sleep provider community.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the COPD measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272) and not including PQRS #130 in the measures group as proposed.

Comment: Total Knee Replacement Measures Group—One commenter expressed support for the Total Knee Replacement measures group, including PQRS measures #130: Documentation of Current Medications in the Medical Record and #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention. They did suggest that in future year's measure #226 be replaced with a measure similar to the functional status assessment for knee replacement measure finalized in the EHR Incentive Program Stage 2 Final Rule. CMS appreciates the commenters' suggestion.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Total Knee Replacement measures group for 2014 as finalized in the CY 2013 PFS final rule (77 FR 69272), without PQRS #130 and PQRS #226 in the measures group as proposed.

Comment: General Surgery Measures Group—We received several comments supporting the inclusion of a General Surgery measures group.

Response: Based on comments received and the decision to not finalize the proposal to increase the number of measures in a measures group from four to six, we are finalizing the General Surgery measures group for 2014, and not including PQRS measure # 130: Documentation of Current Medications in the Medical Record, PQRS measure #226: Preventive Care in the measures group as proposed. Additionally, CMS has decided to combine the proposed Gastrointestinal Surgery measures group with the General Surgery measures group to decrease reporting burden on eligible professionals. The Iatrogenic Injury to Adjacent Organ/Structure measure proposed for the General Surgery and Gastrointestinal Surgery measures groups is not being finalized.

Comment: Optimizing Patient Exposure to Ionizing Radiation Measures Group—Several commenters expressed support for this measures group, stating it will allow for more reporting opportunities for radiologists and will encourage physicians to monitor and consider prior radiation exposure, in an effort to reduce unnecessary radiation exposure to Medicare beneficiaries. One commenter agreed with the intent of the measures group but questioned the inclusion of the following measure: Count of Potential High Dose Radiation Imaging Studies, and suggested replacing it with three existing PQRS measures: #322 Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients, #323 Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI) and #324 Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients. CMS appreciates the commenters' suggestions, but since we did not propose including these measures as part of the measures group in the CY2014 PFS Proposed Rule, we are not addressing these comments in this final rule. We received several comments supporting the Optimizing Patient Exposure to Ionizing Radiation Measures Group in general; however they encouraged CMS to finalize this measures group only after the individual measures have received NQF endorsement.

Response: While we appreciate the commenters' feedback, we believe there are circumstances (such as when a measure addresses a gap in the PQRS measure set) where we may believe that it is important to include a non-NQF endorsed measure to be available for reporting under PQRS. Section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to include measures available for reporting under PQRS that are not NQF endorsed. Therefore, we are finalizing the Optimizing Patient Exposure to Ionizing Radiation measures group with all of the proposed component measures for 2014.

Comment: Diabetes Measures Group—One commenter recommended not removing PQRS measure #3: Diabetes

Mellitus: High Blood Pressure Control from the Diabetes measures group without adding a measure focused on blood pressure control for people with Diabetes.

Response: CMS appreciates the commenters' suggestions, but disagrees due to CMS' efforts to reduce duplicity in measures and the fact that this measure was not proposed for inclusion in the CY2014 PFS proposed rule. Additionally, CMS is not finalizing the proposal to increase the number of measures in a measures group from four to six. Therefore, CMS is finalizing the Diabetes measures group without PQRS measure #130: Documentation of Current Medications in the Medical Record.

The following measures groups received no public comments:

- Back Pain Measures Group—measures #130 and #131 will not be finalized for inclusion in this measures group as proposed.
- Hepatitis C Measures Group—measures #130 and #226 will not be finalized for inclusion in this measures group as proposed.
- Heart Failure Measures Group—measures #128 and #130 will not be finalized for inclusion in this measures group as proposed.
- Coronary Artery Disease (CAD) Measures Group—measures #128 and #130 will not be finalized for inclusion in this measures group as proposed.
- HIV/AIDS Measures Group—measure #130 will not be finalized for inclusion in this measures group as proposed.
- Inflammatory Bowel Disease Measures Group—this measures group is finalized as proposed.
- Cardiovascular Prevention Measures Group—this measures group is finalized as proposed.
- Oncology Measures Group—this measures group is finalized as proposed.
- Preventive Care Measures Group—this measures group is finalized as proposed.
- Coronary Artery Bypass Graft Measures Group (CABG)—this measures group is finalized as proposed.
- Rheumatoid Arthritis (RA) Measures Group—this measures group is finalized as proposed.

Tables 55 through 79 specify the final measures groups that are reportable for the PQRS for 2014 and beyond. Please note that, as we are not finalizing our proposal to modify the definition of a measures group to require that a measures group contain at least 6 measures, the measures groups we finalized in the CY 2013 PFS final rule (77 FR 69272) will remain unchanged. Please note that, since we are finalizing our proposal to eliminate the reporting of measures groups via claims, all measures groups in the 2014 Physician Quality Reporting System are reportable through registry-based reporting only.

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

TABLE 55—DIABETES MELLITUS MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0059/1	Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	NCQA.
0064/2	Diabetes: Low Density Lipoprotein (LDL–C) Control (<100 mg/dL): Percentage of patients 18–75 years of age with diabetes whose LDL–C was adequately controlled (<100 mg/dL) during the measurement period.	NCQA.
0055/117	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period.	NCQA.
0062/119	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	NCQA.
0056/163	Diabetes: Foot Exam: Percentage of patients aged 18–75 years of age with diabetes who had a foot exam during the measurement period.	NCQA.

Finalized in the CY 2013 PFS final rule (see Table 97 at 77 FR 69273).

TABLE 56—CHRONIC KIDNEY DISEASE (CKD) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA–PCPI.
1668/121	Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period.	AMA–PCPI.
AQA adopted/122	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and proteinuria with a blood pressure <130/80 mmHg OR ≥130/80 mmHg with a documented plan of care.	AMA–PCPI.

TABLE 56—CHRONIC KIDNEY DISEASE (CKD) MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
1666/123	Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA)—Hemoglobin Level >12.0 g/dL: Percentage of calendar months within a 12-month period during which a hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy have a hemoglobin level >12.0 g/dL.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 98 at 77 FR 69273).

TABLE 57—PREVENTIVE CARE MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0046/39	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	AMA–PCPI/NCQA.
0098/48	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	AMA–PCPI/NCQA.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA–PCPI.
0043/111	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA.
N/A/112	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months.	NCQA.
0034/113	Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer.	NCQA.
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is *outside of normal parameters,* a follow-up plan is documented during the encounter or during the previous 6 months of the encounter.	
	Normal Parameters: Age 65 years and older BMI >23 and <30; Age 18–64 years BMI ≥18.5 and <25.	CMS.
AQA Adopted/173	Preventive Care and Screening: Unhealthy Alcohol Use—Screening: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months.	AMA–PCPI.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 99 at 77 FR 69273).

TABLE 58—CORONARY ARTERY BYPASS GRAFT (CABG) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0134/43	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	STS.
0236/44	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	CMS.
0129/164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation >24 hours.	STS.

TABLE 58—CORONARY ARTERY BYPASS GRAFT (CABG) MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
0130/165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	STS.
0131/166	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a *post-operative* stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	STS.
0114/167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	STS.
0115/168	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	STS.
0116/169	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication.	STS.
0117/170	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers.	STS.
0118/171	Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen.	STS.

Finalized in the CY 2013 PFS final rule (see Table 100 at 77 FR 69274).

TABLE 59—RHEUMATOID ARTHRITIS (RA) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0054/108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD.	NCQA.
AQA adopted/176	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	AMA–PCPI.
AQA adopted/177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.	AMA–PCPI.
AQA adopted/178	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	AMA–PCPI.
AQA adopted/179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	AMA–PCPI.
AQA adopted/180	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 101 at 77 FR 69274).

TABLE 60—PERIOPERATIVE CARE MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0270/20	Perioperative Care: Timing of Prophylactic Parenteral Antibiotic—Ordering Physician: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required).	AMA–PCPI/NCQA.
0268/21	Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	AMA–PCPI/NCQA.
0271/22	Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures): Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time.	AMA–PCPI/NCQA.
0239/23	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	AMA–PCPI/NCQA.

Finalized in the CY 2013 PFS final rule (see Table 102 at 77 FR 69275).

TABLE 61—BACK PAIN MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0322/148	Back Pain: Initial Visit: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain.	NCQA.
0319/149/	Back Pain: Physical Exam: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain.	NCQA.
0314/150	Back Pain: Advice for Normal Activities: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain.	NCQA.
0313/151	Back Pain: Advice Against Bed Rest: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain.	NCQA.

Finalized in the CY 2013 PFS final rule (see Table 103 at 77 FR 69275).

TABLE 62—HEPATITIS C MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0395/84	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV) RNA testing was performed within 12 months prior to initiation of antiviral treatment.	AMA–PCPI.
0396/85	Hepatitis C: HCV Genotype Testing Prior to Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment.	AMA–PCPI.

TABLE 62—HEPATITIS C MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
0398/87	Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4–12 Weeks After Initiation of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4–12 weeks after the initiation of antiviral treatment.	AMA–PCPI.
0399/183	Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV): Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 104 at 77 FR 69275).

TABLE 63—HEART FAILURE (HF) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0081/5	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at *each* hospital discharge.	AMA–PCPI/ACCF/AHA.
0083/8	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at *each* hospital discharge.	AMA–PCPI/ACCF/AHA.
0079/198	Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment: Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12 month period.	AMA–PCPI/ACCF/AHA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 105 at 77 FR 69276).

TABLE 64—CORONARY ARTERY DISEASE (CAD) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0067/6	Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel.	AMA–PCPI/ACCF/AHA.
0074/197	Coronary Artery Disease (CAD): Lipid Control: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL–C result <100 mg/dL OR patients who have a LDL–C result ≥100 mg/dL and have a documented plan of care to achieve LDL–C <100 mg/dL, including at a minimum the prescription of a statin.	AMA–PCPI/ACCF/AHA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
N/A/242	Coronary Artery Disease (CAD): Symptom Management: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period.	AMA–PCPI/ACCF/AHA.

Finalized in the CY 2013 PFS final rule (see Table 106 at 77 FR 69276).

TABLE 65—ISCHEMIC VASCULAR DISEASE (IVD) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0068/204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period.	NCQA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
0018/236	Controlling High Blood Pressure: Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period..	NCQA.
0075/241	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL–C Control (<100 mg/dL): Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL–C was adequately controlled (<100 mg/dL).	NCQA.

Finalized in the CY 2013 PFS final rule (see Table 107 at 77 FR 69277).

TABLE 66—HIV/AIDS MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0404/159	HIV/AIDS: CD4+ Cell Count or CD4+ Percentage Performed: Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months.	NCQA.
0405/160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis.	NCQA.
0409/205	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection.	AMA–PCPI/NCQA.
2082/N/A	HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	HRSA.
2083/N/A	Prescription of HIV Antiretroviral Therapy: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year.	HRSA.
2079/N/A	HIV Medical Visit Frequency: Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	HRSA.
2080/N/A	Gap in HIV Medical Visits: Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months.	HRSA.

Finalized in the CY 2013 PFS final rule (see Table 108 at 77 FR 69277).

TABLE 67—ASTHMA MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0047/53	Asthma: Pharmacologic Therapy for Persistent Asthma—Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who were prescribed long-term control medication.	AMA–PCPI/NCQA.

TABLE 67—ASTHMA MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
0001/64	Asthma: Assessment of Asthma Control—Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least once during the measurement period for asthma control (comprising asthma impairment and asthma risk).	AMA–PCPI/NCQA.
N/A/231	Asthma: Tobacco Use: Screening—Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma (or their primary caregiver) who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period.	AMA–PCPI/NCQA.
N/A/232	Asthma: Tobacco Use: Intervention—Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were identified as tobacco users (or their primary caregiver) who received tobacco cessation intervention at least once during the one-year measurement period.	AMA–PCPI/NCQA.

Finalized in the CY 2013 PFS final rule (see Table 109 at 77 FR 69277).

TABLE 68—CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0091/51	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented.	AMA–PCPI.
0102/52	Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator.	AMA–PCPI.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA–PCPI.
0043/111	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 110 at 77 FR 69278).

TABLE 69—INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
N/A/269	Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period.	AGA.
N/A/270	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year.	AGA.
N/A/271	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury—Bone Loss Assessment: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year.	AGA.
N/A/272	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization: Percentage of patients aged 18 years and older with inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year.	AGA.

TABLE 69—INFLAMMATORY BOWEL DISEASE (IBD) MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/273	Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received.	AGA.
N/A/274	Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	AGA.
N/A/275	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within 1 year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.	AGA.

Finalized in the CY 2013 PFS final rule (see Table 111 at 77 FR 69278).

TABLE 70—SLEEP APNEA MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
N/A/276	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness.	AMA–PCPI/NCQA.
N/A/277	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	AMA–PCPI/NCQA.
N/A/278	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.	AMA–PCPI/NCQA.
N/A/279	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	AMA–PCPI/NCQA.

Finalized in the CY 2013 PFS final rule (see Table 112 at 77 FR 69279).

TABLE 71—DEMENTIA MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
N/A/280	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period.	AMA–PCPI.
N/A/281	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI.
N/A/282	Dementia: Functional Status Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period.	AMA–PCPI.
N/A/283	Dementia: Neuropsychiatric Symptom Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period.	AMA–PCPI.
N/A/284	Dementia: Management of Neuropsychiatric Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period.	AMA–PCPI.
N/A/285	Dementia: Screening for Depressive Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period.	AMA–PCPI.

TABLE 71—DEMENTIA MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/286	Dementia: Counseling Regarding Safety Concerns: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	AMA–PCPI.
N/A/287	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period.	AMA–PCPI.
N/A/288	Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 113 at 77 FR 69279).

TABLE 72—PARKINSON'S DISEASE MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
N/A/289	Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review: All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually.	AAN.
N/A/290	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually.	AAN.
N/A/291	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually.	AAN.
N/A/292	Parkinson's Disease: Querying about Sleep Disturbances: All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually.	AAN.
N/A/293	Parkinson's Disease: Rehabilitative Therapy Options: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually.	AAN.
N/A/294	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually.	AAN.

Finalized in the CY 2013 PFS final rule (see Table 114 at 77 FR 69279).

TABLE 73—HYPERTENSION MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
N/A/295	Hypertension: Use of Aspirin or Other Antithrombotic Therapy: Percentage of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for aspirin or other antithrombotic therapy who were prescribed aspirin or other antithrombotic therapy.	ABIM.
N/A/296	Hypertension: Complete Lipid Profile: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within *60 months*.	ABIM.
N/A/297	Hypertension: Urine Protein Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within *36 months*.	ABIM.
N/A/298	Hypertension: Annual Serum Creatinine Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within *12 months*.	ABIM.

TABLE 73—HYPERTENSION MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
N/A/299	Hypertension: Diabetes Mellitus Screening Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within *36 months*.	ABIM.
N/A/300	Hypertension: Blood Pressure Control: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension whose most recent blood pressure was under control (< 140/90 mmHg).	ABIM.
N/A/301	Hypertension: Low Density Lipoprotein (LDL–C) Control: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension whose most recent LDL cholesterol level was under control (at goal).	ABIM.
N/A/302	Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within *12 months*.	ABIM.

Finalized in the CY 2013 PFS final rule (see Table 115 at 77 FR 69280).

TABLE 74—CARDIOVASCULAR PREVENTION MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0064/2	Diabetes: Low Density Lipoprotein (LDL–C) Control (<100 mg/dL): Percentage of patients 18–75 years of age with diabetes whose LDL–C was adequately controlled (<100 mg/dL) during the measurement.	NCQA.
0068/204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period.	NCQA.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.
0018/236	Controlling High Blood Pressure: Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	NCQA.
0075/241	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL–C Control (<100 mg/dL): Percentage of patients 18 years of age andolder who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL–C was adequately controlled (<100 mg/dL).	NCQA.
N/A/317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated.	CMS.

Finalized in the CY 2013 PFS final rule (see Table 116 at 77 FR 69280).

TABLE 75—CATARACTS MEASURES GROUP

NQF/PQRS	Measure title and description	Measure developer
0565/191	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	AMA–PCPI/NCQA.

TABLE 75—CATARACTS MEASURES GROUP—Continued

NQF/PQRS	Measure title and description	Measure developer
0564/192	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	AMA–PCPI/NCQA.
N/A/303	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	AAO.
N/A/304	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	AAO.

Finalized in the CY 2013 PFS final rule (see Table 117 at 77 FR 69281).

TABLE 76—ONCOLOGY MEASURES GROUP

NQF/PQRS	Measure title and cescription	Measure developer
0387/71	Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA–PCPI/ASCO/NCCN.
0385/72	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients: Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.	AMA–PCPI/ASCO/NCCN.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	AMA–PCPI.
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list *must* include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND *must* contain the medications' name, dosage, frequency and route of administration.	CMS.
0384/143	Oncology: Medical and Radiation—Pain Intensity Quantified: Percentage of patients, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	AMA–PCPI.
0383/144	Oncology: Medical and Radiation—Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	AMA–PCPI.
0386/194	Oncology: Cancer Stage Documented: Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period.	AMA–PCPI/ASCO.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months *AND* who received cessation counseling intervention if identified as a tobacco user.	AMA–PCPI.

Finalized in the CY 2013 PFS final rule (see Table 118 at 77 FR 69281).

TABLE 77—TOTAL KNEE REPLACEMENT MEASURES GROUP

NQF/PQRS	Measure title	Measure developer
N/A/N/A	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy prior to the procedure.	AAHKS.
N/A/N/A	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of Deep Vein Thrombosis, Pulmonary Embolism, Myocardial Infarction, Arrhythmia and Stroke.	AAHKS.
N/A/N/A	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	AAHKS.
N/A/N/A	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients regardless of age or gender undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of prosthetic implant.	AAHKS.

Finalized in the CY 2013 PFS final rule (see Table 120 at 77 FR 69283).

TABLE 78—GENERAL SURGERY MEASURES GROUP

NQF/PQRS	Measure title	Measure developer
N/A/N/A	Anastomotic Leak Intervention: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	ACS.
N/A/N/A	Unplanned Reoperation within the 30 Day Postoperative Period: Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	ACS.
N/A/N/A	Unplanned Hospital Readmission within 30 Days of Principal Procedure: Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	ACS.
N/A/N/A	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	ACS.
N/A/N/A	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical database-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	ACS.

TABLE 79—OPTIMIZING PATIENT EXPOSURE TO IONIZING RADIATION MEASURES GROUP

NQF/PQRS	Measure title	Measure developer
N/A/N/A	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	AMA–PCPI.
N/A/N/A	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies: Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	AMA–PCPI.

TABLE 79—OPTIMIZING PATIENT EXPOSURE TO IONIZING RADIATION MEASURES GROUP—Continued

NQF/PQRS	Measure title	Measure developer
N/A/N/A	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry: Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements.	AMA–PCPI.
N/A/N/A	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes: Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study.	AMA–PCPI.
N/A/N/A	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.	AMA–PCPI.
N/A/N/A	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (eg, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.	AMA–PCPI.

c. Final Measures Available for Reporting in the GPRO Web Interface

For ease of reference, Table 80 specifies the measures that are available for reporting in the GPRO web interface for 2014 and beyond. Please note that this is a total list of the measures that will be reported by a group practice using the GPRO web interface in 2014, and all measures contained within this table were previously finalized in the CY 2013 PFS final rule (77 FR 69269).

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TABLE 80: Measures in the Group Practice Reporting Option Web Interface for 2014 and Beyond

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description¥	Measure Steward	Other Quality Reporting Programs
0059/ 1	Diabetes Mellitus	Effective Clinical Care	**Diabetes: Hemoglobin A1c Poor Control:** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period	NCQA	MU2 ACO
0083/ 8	Heart Failure	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at **each** hospital discharge	AMA- PCPI/ ACCF/ AHA	MU2 ACO
0097/ 46	Care Coordination/ Patient Safety	Patient Safety	**Medication Reconciliation:** Percentage of patients aged 65 years and older **discharged from any inpatient facility** (e.g. hospital, skilled nursing facility, or rehabilitation facility) and **seen within 30 days following discharge** in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented	AMA- PCPI/ NCQA	ACO

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description*	Measure Steward	Other Quality Reporting Programs
0041/ 110	Preventive Care	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI	MU2 ACO
0043/ 111	Preventive Care	Effective Clinical Care	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal **vaccine**	NCQA	MU2 ACO
N/A/ 112	Preventive Care	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months	NCQA	MU2 ACO
0034/ 113	Preventive Care	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer	NCQA	MU2 ACO
0066/ 118	Coronary Artery Disease	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI/ACCF/AHA	ACO

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description*	Measure Steward	Other Quality Reporting Programs
0421/ 128	Preventive Care	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up:** Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter **Normal Parameters**: Age 65 years and older BMI ≥ 23 and < 30; Age 18-64 years BMI ≥ 18.5 and < 25	CMS	MU2 ACO
0418/ 134	Preventive Care	Community/Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen	CMS	MU2 ACO
0074/ 197	Coronary Artery Disease	Effective Clinical Care	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100mg/dL, including at a minimum the prescription of a statin	AMA- PCPI/ ACCF/ AHA	ACO

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description*	Measure Steward	Other Quality Reporting Programs
0068/ 204	Ischemic Vascular Disease	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period	NCQA	MU2 ACO Million Hearts
0028/ 226	Preventive Care	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	MU2 ACO Million Hearts
0018/ 236	Hypertension	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	NCQA	MU2 ACO Million Hearts

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description*	Measure Steward	Other Quality Reporting Programs
0075/ 241	Ischemic Vascular Disease	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Complete Lipid Profile and (LDL-C) Control (<100 mg/dL):** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL)	NCQA	MU2 ACO Million Hearts
N/A/ 317	Preventive Care	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the measurement period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated	CMS	MU2 ACO Million Hearts
0101/ 318	Care Coordination/ Patient Safety	Patient Safety	**Falls: Screening for Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period	NCQA	MU2 ACO

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description¥	Measure Steward	Other Quality Reporting Programs
0729/ 319	Diabetes Mellitus	Effective Clinical Care	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: • A1c < 8.0% • LDL < 100 mg/dL • blood pressure < 140/90 mmHg • tobacco non-user and • (for patients with a diagnosis of ischemic vascular disease) daily aspirin use unless contraindicated	MNCM	ACO

¥ Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Registry measure titles and descriptions, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

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d. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

Because we believed these patient surveys are important tools for assessing beneficiary experience of care and outcomes, under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report, we proposed a new satisfactory reporting criterion in this the proposed rule to provide group practices comprised of 25 or more eligible professionals the option to complete the CG CAHPS survey for purposes of satisfying the 2014 PQRS incentive and 2016 PQRS payment adjustment (78 FR 43476). Specifically, we proposed the following 12 summary the survey measures to use for the PQRS program:

- Getting timely care, appointments, and information.
- How well providers Communicate.
- Patient's Rating of Provider.
- Access to Specialists.
- Health Promotion & Education.
- Shared Decision Making.
- Health Status/Functional Status.
- Courteous and Helpful Office Staff.
- Care Coordination.
- Between Visit Communication.
- Helping Your to Take Medication as Directed.
- Stewardship of Patient Resources.

The first seven measures proposed above are the same ones used in the Medicare Shared Savings Programs. We believe it is important to align measures across programs to the extent possible. The remaining five measures proposed above address areas of high importance to Medicare and are areas where patient experience can inform the quality of care related to care coordination and efficiency. We noted that under this proposal, the group practice would bear the cost of having this survey administered. We solicited and received the following public comments on these proposed measures:

Comment: Several commenters generally supported the addition of a GPRO option to report the CG CAHPS survey measures for the 2014 PQRS incentive. However, some commenters have concerns that, since the survey's questions focus on primary care issues, the surveys are not widely applicable to services provided by certain specialists. Some of these commenters requested that, in addition to allowing reporting of the CG CAHPS survey measures, surgical group practices in the GPRO also be allowed to report on the Consumer Assessment of Healthcare Providers Surgical Care Survey (S–CAHPS) as these survey measures are more relevant to their practice.

Response: We appreciate the commenters' positive feedback and are therefore finalizing this proposed criterion, as proposed. For the commenters' request to allow surgical group practices to report on S–CAHPS survey measures, we generally agree that the S–CAHPS survey measures would be more relevant to a surgical group practice than the CG CAHPS measures. Unfortunately, at this time, we cannot introduce the S–CAHPS measures for reporting in the PQRS GPRO for 2014, since the Measure Applications Partnership (MAP) has not yet had an opportunity to review the S–CAHPS survey measures. Please note that section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the entity with a contract with the Secretary under section 1890(a) of the Act (currently that, is the NQF) convene multi-stakeholder groups, currently the MAP, to provide input to the Secretary on the selection of certain categories of quality and efficiency measures. As such, prior to inclusion in the PQRS measure set, the S–CAHPS survey measures must be submitted to the MAP for review.

Comment: One commenter expressed concern with ''survey fatigue.'' This commenter is concerned that some patients will receive multiple surveys

asking very similar questions, which will likely to result in low response rates.

Response: We appreciate the comment and concern raised regarding ''survey fatigue.'' CMS recognizes that there are multiple CAHPS survey efforts and takes steps to ensure that we are not duplicating patients in survey samples, as well as varies the timing in which it disseminates the survey.

Based on the comments received and for the reasons stated previously, we are finalizing the CG CAHPS measures, as proposed. A full description of the CG CAHPS survey measures is available at *http://acocahps.cms.gov/Content/Default.aspx#aboutSurvey*.

11. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Participation in a Qualified Clinical Data Registry for 2014 and Beyond for Individual Eligible Professionals

For the measures for which eligible professionals participating in a qualified clinical data registry must report, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the American Tax Relief Act of 2012, provides that the Secretary shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a qualified clinical data registry. Section 1848(m)(3)(E) of the Act, as added by section 601(b) of the ATRA, provides some flexibility with regard to the types of measures applicable to satisfactory participation in a qualified clinical data registry, by specifying that for measures used by a qualified clinical data registry, sections 1890(b)(7) and 1890A(a) of the Act shall not apply, and measures endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act may be used.

We proposed to provide to qualified clinical data registries flexibility with regard to choosing the quality measures data available for individual eligible professionals to choose from to report to CMS using these qualified clinical data registries (78 FR 43476). We believe it is preferable for the qualified clinical data registries with flexibility in selecting measures since we believe these clinical data registries would know best what measures should be reported to achieve the goal of improving the quality of care furnished by their eligible professionals. Although we proposed to allow these clinical data registries to determine the quality measures from which individual eligible professionals would choose to have reported to CMS, to ensure that CMS receives the same type of data that could be uniformly analyzed by CMS and sufficient measure data, we believe it is important to set parameters on the measures to be reported on and the types of measures should be reported to CMS. Therefore, we proposed requirements for the measures that would have to be reported to CMS by a qualified clinical data registry for the purpose of its individual eligible professionals meeting the criteria for satisfactory participation under the PQRS (78 FR 43476–43477). Below we have listed those proposed requirements and provided a summary of the comments received and our responses directly following each proposed requirement. We also received the following general comments on these proposals:

Comment: Several commenters generally supported our proposal to allow qualified clinical data registries to choose which measures will be reported to the PQRS on behalf of its participating eligible professional, as this provides flexibility in this reporting option. However, one commenter opposed allowing qualified clinical data registries to choose which measures its participants will report for purposes of the PQRS, because the measures reported by a qualified clinical data registry on behalf of an eligible professional may not be as robust as the measures finalized in the PQRS measure set.

Response: We appreciate the commenters' positive feedback and agree that it provides flexibility. For the opposing comment, we understand the commenter's concerns and expect that the measures reported by qualified clinical data registries are as robust and meaningful as those finalized in the PQRS measure set. We are finalizing requirements—such as the requirements related to bench marking and the risk adjustment of certain measures—for the qualified clinical data registries that ensure that entities selected to become qualified clinical data registries have measures that are as robust as the measures contained in the PQRS measure set. Therefore, we believe our desire to provide flexibility in the measures that may be reported by a qualified clinical data registry outweighs our concern that the measures reported by a qualified clinical data registry may not be as robust as the measures finalized in the PQRS measure set.

We invited and received the following public comments on the proposed requirements for the measures the qualified clinical data registry would report to CMS for the individual eligible professional:

- The qualified clinical data registry must have at least 9 measures, covering at least 3 of the 6 NQS domains, available for reporting. The 6 NQS domains are as follows:

++ *Person and Caregiver-Centered Experience and Outcomes.* These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

++ *Patient Safety.* These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

++ *Communication and Care Coordination.* These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication.

++ *Community/Population Health.* These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

++ *Efficiency and Cost Reduction.* These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

++ *Effective Clinical Care.* These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We solicited and received the following public comment on this proposal:

Comment: Some commenters supported our proposal to require that measures are reported according to their NQS domains. However, some commenters suggested that we use domains created by AHRQ rather than the NQS domains.

Response: We appreciate the commenters' support. For the commenters who suggested that we use domains created by AHRQ, in an effort to align how these measures are analyzed, we prefer to use the NQS domains. Based on the comments received and since we are finalizing satisfactory participation criterion relating to the reporting of 9 measures covering at least 3 NQS domains, we are finalizing the requirement that a qualified clinical data registry must have at least 9 measures, covering at least 3 of the 6 NQS domains, available for reporting, as proposed.

• The qualified clinical data registry must have at least 1 outcome measure available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost). We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supportedthis proposal. Some commenters requested further clarification regarding the definition of an outcome measure.

Response: An outcome measure, as defined within the CMS Measures Management System Blueprint v10.0, indicates the result of the performance (or nonperformance) of functions or processes. It is a measure that focuses on achieving a particular state of health. PY 2014 examples of outcome measures within the PQRS include Measure #1: Diabetes: Hemoglobin A1c Poor Control, Measure #258: Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7), or Measure #303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Please note that, even though the one of the criterion for satisfactory participation in a qualified clinical data registry does not require the reporting of at least 1 outcome measure, we are still finalizing this requirement, as proposed.

• The qualified clinical data registry may report on process measures, which are measures that focus on a process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome. We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supported this proposal.

Response: We appreciate the commenters' support for this proposal. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The outcome and process measures reported must contain denominator data. That is, the lower portion of a fraction used to calculate a rate, proportion, or ratio. The denominator must describe the population eligible (or episodes of care) to be evaluated by the measure. This should indicate age, condition, setting, and timeframe (when applicable). For example, ''Patients aged 18 through 75 years with a diagnosis of diabetes.'' We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supported this proposal. Other commenters suggested that this requirement was overly restrictive. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured (such as requiring that measures contain denominator data).

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, particularly containing denominator data, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The outcome and process measures reported must contain numerator data. That is, the upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator must detail the quality clinical action expected that satisfies the condition(s) and is the focus of the measurement for each patient, procedure, or other unit of measurement established by the denominator (that is, patients who received a particular service or providers that completed a specific outcome/process). We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supported this proposal. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured (such as requiring that measures contain numerator data).

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, particularly containing numerator data, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The qualified clinical data registry must provide denominator exceptions for the measures, where appropriate. That is, those conditions that should remove a patient, procedure or unit of measurement from the denominator of the performance rate only if the numerator criteria are not met. Denominator exceptions allow for adjustment of the calculated score for those providers with higher risk populations. Denominator exceptions allow for the exercise of clinical judgment and should be specifically defined where capturing the information in a structured manner fits the clinical workflow. Generic denominator exception reasons used in measures fall into three general categories: Medical, Patient, or System reasons. We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supported this proposal. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform

to the way a PQRS measure is structured.

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The qualified clinical data registry must provide denominator exclusions for the measures for which it will report to CMS, where appropriate. That is, those patients with conditions who should be removed from the measure population and denominator before determining if numerator criteria are met. (For example, Patients with bilateral lower extremity amputations would be listed as a denominator exclusion for a measure requiring foot exams.) We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supported this proposal. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured.

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The qualified clinical data registry must provide to CMS descriptions for the measures for which it will report to CMS by no later than March 31, 2014. The descriptions must include: name/title of measures, NQF # (if NQF endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions and denominator exclusions of the measure. We solicited and received public comment on this proposal:

Comment: Some commenters generally supported this proposal.

Response: We appreciate the commenters' support for this proposal. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

We note that last year we introduced the reporting of composite measures in the PQRS measure set. While we have had years of experience analyzing measures structured like traditional PQRS measures, we are only in the initial stages of learning how to analyze composite measures. To the extent that we qualified clinical data registries wish to submit composite measures for reporting for the PQRS, we are requiring that the qualified clinical data registry calculate the composite score for CMS and provide to CMS the formula used for calculating the composite score. It is necessary that qualified clinical data registries be able to calculate the composite score, as well as provide us with their formula for calculating the score as CMS will likely be unable to analyze the data received on composite measures.

Please note that we are specifying the final requirements we are adopting regarding quality measures for satisfactory participation in a qualified clinical data registry under § 414.90(g).

12. PQRS Informal Review

Section 414.90(j) provides that eligible professionals and group practices may request an informal review of the determination that an eligible professional or group practice did not satisfactorily submit data on quality measures under the PQRS. Because we believe it is important to also allow eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry to be able to request an informal review of the determination that the eligible professional satisfactorily participated in a qualified clinical data registry, we proposed to modify § 414.90(j) to allow individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review. We solicited and received public comment on this proposal:

Comment: Several commenters supported our proposal to modify § 414.90(j) to allow individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review.

Response: Based on the commenters' positive feedback and for the reasons we set forth above, we are finalizing this proposal, as proposed. We are therefore modifying newly designated § 414.90(m) to specify allowing individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review.

I. Electronic Health Record (EHR) Incentive Program

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

For CY 2012 and subsequent years, § 495.8(a)(2)(ii) requires an EP to successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable. In the EHR Incentive Program Stage 2 Final Rule, we established clinical quality measure reporting options for the Medicare EHR Incentive Program for CY 2014 and subsequent years that include one individual reporting option that aligns with the PQRS's EHR reporting option (77 FR 54058) and two group reporting options that align with the PQRS GPRO and Medicare Shared Savings Program (MSSP) and Pioneer ACOs (77 FR 54076 to 54078). In the CY 2014 PFS proposed rule, we proposed two additional aligned options for EPs to report CQMs for the Medicare EHR Incentive Program for CY 2014 and subsequent years with the intention of minimizing the reporting burden on EPs (78 FR 43479–43481). Please note that, during the comment period following the proposed

rule, we received comments that were not related to our specific proposals for the EHR Incentive Program in the CY 2014 PFS proposed rule. While we appreciate the commenters' feedback, these comments will not be specifically addressed in this CY 2014 PFS final rule with comment period, as they are beyond the scope of this rule.

1. Qualified Clinical Data Registry Reporting Option

For purposes of meeting the CQM reporting component of meaningful use for the Medicare EHR Incentive Program for the EHR reporting periods in 2014 and subsequent years, we proposed to allow EPs to submit CQM information using qualified clinical data registries, according to the proposed definition and requirements for qualified clinical data registries under the PQRS (78 FR 43360). We refer readers to the discussion in the proposed rule for further explanation of the PQRS qualified clinical data registry reporting option and the reasons given in support of our proposals (78 FR 43479).

In addition to the criteria that are ultimately established for PQRS, we proposed the following additional criteria that an EP who seeks to report CQMs for the Medicare EHR Incentive Program using a qualified clinical data registry must satisfy: (1) The EP must use CEHRT as required under the Medicare EHR Incentive Program; (2) the CQMs reported must be included in the Stage 2 final rule (see Table 8, 77 FR 54069) and use the same electronic specifications established for the EHR Incentive Program; (3) report 9 CQMs covering at least 3 domains; (4) if an EP's CEHRT does not contain patient data for at least 9 CQMs covering at least 3 domains, then the EP must report the CQMs for which there is patient data and report the remaining CQMs as ''zero denominators'' as displayed by the EP's CEHRT; and (5) an EP must have CEHRT that is certified to all of the certification criteria required for CQMs, including certification of the qualified clinical data registry itself for the functions it will fulfill (for example, calculation, electronic submission). We noted that these proposed additional criteria are already final policies for the CQM reporting options that we established for EPs in the EHR Incentive Program Stage 2 final rule. We referred readers to that final rule for further explanation of the policies related to clinical quality measure reporting under the EHR Incentive Program (77 FR 54049–54089). The electronic specifications for the clinical quality measures can be found at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*.

We proposed the qualified clinical data registry reporting option only for those EPs who are beyond their first year of demonstrating meaningful use (MU). For purposes of avoiding a payment adjustment under Medicare, EPs who are in their first year of demonstrating MU in the year immediately preceding a payment adjustment year must satisfy their CQM reporting requirements by October 1 of such preceding year (for example, by October 1, 2014 to avoid a payment adjustment in 2015). We noted that the proposed qualified clinical data registry reporting option would not enable an EP to meet the deadline to avoid a payment adjustment because these qualified clinical data registries would be submitting data on CQMs by the last day of February following the 2014 PQRS incentive reporting periods, which would occur after October 1, 2013. Therefore, EPs who are first-time meaningful EHR users must report CQMs via attestation as established in the EHR Incentive Program Stage 2 final rule (77 FR 54050). The reporting periods established in the EHR Incentive Program Stage 2 final rule would continue to apply to EPs who would choose to report CQMs under this proposed qualified clinical data registry reporting option for purposes of the Medicare EHR Incentive Program (77 FR 54049–54051). We noted that this may not satisfy requirements for other quality reporting programs that have established 12-month reporting periods, such as the PQRS.

As EPs are required to use CEHRT under section 1848(o)(2)(A)(iii) of the Act, we proposed that, for the Medicare EHR Incentive Program, an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP's CEHRT.

We solicited and received the following public comments on these proposals:

Comment: One commenter opposed our general proposal to allow EPs to submit CQM information using qualified clinical data registries, according to the definition and requirements for qualified clinical data registries under the PQRS. The commenter indicated that incorporating a qualified clinical data registry option for the EHR Incentive Program would undermine the integrity of the requirements to meet the CQM component of meaningful use. Specifically, the commenter believed the proposed requirements to participate in a qualified clinical data registry were less stringent than the requirements finalized in the EHR Incentive Program Stage 2 final rule with regard to CQM reporting.

Response: We disagree with the commenter's concerns and do not believe the qualified clinical data registry option would be less stringent than the other reporting options already established in the EHR Incentive Program Stage 2 final rule. To the contrary, as discussed above, we proposed certain additional requirements for EPs who report using a qualified clinical data registry for purposes of the Medicare EHR Incentive Program, which were established previously for other reporting methods in the EHR Incentive Program Stage 2 final rule, such as the requirement that an EP that reports using a qualified clinical data registry must use a product that is CEHRT.

Comment: Several commenters opposed our proposed requirement to only allow reporting of the CQMs included in the Stage 2 final rule (see Table 8, 77 FR 54069), as well as to use the same electronic specifications established for the EHR Incentive Program. The commenters believed EPs should be allowed to report on measures outside of the CQMs included in the Stage 2 final rule to align with the reporting criteria finalized under the PQRS that allows qualified clinical data registries to report on measures outside the PQRS and EHR Incentive Program measure set.

Response: We understand the commenters' desire to create flexibility in the measures that may be reported under this qualified clinical data registry option.

However, the CQMs selected for the EHR Incentive Program were established in the Stage 2 final rule prior to the passage of the American Taxpayer Relief Act of 2012, and we have not proposed to add additional measures to that set. Therefore, we are finalizing this proposal. Please note that, in addition, as we also finalized for EPs using the qualified clinical data registry reporting mechanism for the PQRS, an EP who chooses to report using a qualified clinical data registry to meet the CQM component of meaningful use in 2014 must report the most recent version (that is, the June 2013 version) of the electronic specification of the measures. The exception to this policy is for the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone

Receptor (ER/PR) Positive Breast Cancer (NQF 0387). As explained below, since CMS discovered an error in this measure, EPs reporting this measure must use the December 2012 version of this CQM.

We understand the commenters' desire to allow more flexibility in reporting via a qualified clinical data registry and, in the future, we will work towards developing a more flexible program policies and certification criteria that would allow eCQMs developed by QCDRs to be reported to CMS in future rulemaking.

Comment: The majority of the commenters supported this proposal. Many of these commenters were pleased to see a qualified clinical data registry reporting option for the EHR Incentive Program that aligns with the qualified clinical data registry option for the PQRS.

Response: We appreciate the commenters' positive feedback.

Comment: Some commenters opposed our proposed requirement that an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP's CEHRT. Some of these commenters believe this requirement would bring the qualified clinical data registry option for the EHR Incentive Program out of alignment with the PQRS qualified clinical data registry option for 2014.

Response: Indeed, this additional requirement departs from the product and vendor requirements for a qualified clinical data registry for the PQRS in 2014. However, as we noted in the CY 2014 PFS proposed rule, under section 1848(o)(2)(A)(iii) of the Act, EPs are required to use CEHRT to submit information on clinical quality measures for the EHR Incentive Program. The 2014 Edition certification criteria established by the ONC set the requirements for certification that cover the functionality needed to ''capture and export'' (45 CFR 170.314(c)(1)), ''import and calculate'' (45 CFR 170.314(c)(2)), and for ''electronic submission'' (45 CFR 170.314(c)(3)) of each CQM that will be reported. In order for the EP's CEHRT to meet these criteria, the qualified clinical data registry would need to test and certify to the functionality that it will fulfill for the EP's CQM reporting, and the qualified clinical data registry's certified module would need to be part of the EP's CEHRT.

After consideration of the public comments received, we are finalizing as proposed our proposal to allow EPs to submit CQM information for purposes of the Medicare EHR Incentive Program beginning with the reporting periods in 2014 using qualified clinical data registries, according to the definition and requirements for qualified clinical data registries under the PQRS discussed in section IV.I. of this final rule with comment period and with the additional criteria for the EHR Incentive Program discussed above. We are finalizing this reporting option only for EPs who are beyond their first year of demonstrating meaningful use.

The registry will need to be certified for the CQM criteria listed at 45 CFR 170.314(c)(2) (''import and calculate'') for each CQM that will be submitted and 45 CFR 170.314(c)(3) (''electronic submission''). EPs will still need to include a certified EHR Module as part of their CEHRT that is certified to the CQM criteria listed at 45 CFR 170.314(c)(1) (''capture and export'') for each of the CQMs that would be submitted to CMS for the purposes of meeting the CQM requirements of the Medicare EHR Incentive Program. If the qualified clinical data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry would need to be certified to the ''capture and export'' criteria listed at 45 CFR 170.314(c)(1), and the certified EHR Module must be part of the EP's CEHRT. Please note that, similar to what is finalized for the PQRS in this final rule with comment period, a qualified clinical data registry would be required to submit quality measures data in a QRDA–III format as proposed (78 FR 43480) and finalized in this final rule with comment period. Although we mentioned allowing for submission of quality measures data in a QRDA–I format, we are not finalizing the proposal to allow for submission of quality measures data in a QRDA–I format.

2. Group Reporting Option—Comprehensive Primary Care Initiative

The Comprehensive Primary Care (CPC) Initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, CMS will pay participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, State, and other federal insurance plans are also offering support to primary care practices that provide high-quality primary care. There are approximately 500 CPC participants across 7 health care markets in the U.S. More details on the CPC Initiative can be found at *http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html*.

Under the CPC Initiative, CPC practice sites are required to report to CMS a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (77 FR 54069–54075). In a continuing effort to align quality reporting programs and innovation initiatives, we propose to add a group reporting option for CQMs to the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a CPC practice site that successfully submits at least 9 electronically specified CQMs covering 3 domains. We proposed that each of the EPs in the CPC practice site would satisfy the CQM reporting component of meaningful use for the relevant reporting period if the CPC practice site successfully submits and meets the reporting requirements of the CPC Initiative. We proposed that only those EPs who are beyond their first year of demonstrating meaningful use may use this proposed CPC group reporting option, for the reasons explained in the preceding section in regard to avoiding a payment adjustment under Medicare. We proposed that EPs who successfully submit as part of a CPC practice site in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy their CQM reporting requirement for the Medicare EHR Incentive Program.

If a CPC practice site fails the requirements established for the CPC Initiative, we noted that the EPs who are part of the site would have the opportunity to report CQMs per the requirements and deadlines established in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (77 FR 54049). We invited and received the following public comments on these proposals:

Comment: Commenters generally supported our proposal to add a group reporting option for CQMs for the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a CPC practice site that successfully submits at least 9 electronically specified CQMs covering 3 domains. Commenters were also pleased that, should a CPC practice site fails the requirements established for the CPC Initiative, EPs in the practice site would still have the opportunity to report CQMs per the requirements

established in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014. These commenters are pleased that we are proposing to give these EPs another mechanism by which they can meet their reporting requirements under the EHR Incentive Program if they do not meet those requirements vis-à-vis their participation in the CPC Initiative.

Response: We appreciate the commenters' support for this proposal. In consideration of the comments received and for the reasons stated previously, we are finalizing a group reporting option for the Medicare EHR Incentive Program, beginning in CY 2014 that is aligned with the CPC Initiative. Under this option, EPs that successfully report at least 9 electronically specified CQMs covering at least 3 domains for the relevant reporting period as part of a CPC practice site in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. EPs reporting under the aligned group reporting option can only report on CQMs that were selected for the EHR Incentive Program in the Stage 2 final rule. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the requirements established for the EHR Incentive Program in the Stage 2 final rule. Additionally, only those EPs who are beyond their first year of demonstrating meaningful use may use this CPC group reporting option. Please note that the CPC practice sites must submit the CQM data in the form and manner required by the CPC Initiative. Therefore, whether the CPC practice site requires electronic submission or attestation of CQMs, the CPC practice site must submit the CQM data in the form and manner required by the CPC Initiative.

3. Reporting of Electronically Specified Clinical Quality Measures for the Medicare EHR Incentive Program

In the EHR Incentive Program Stage 2 final rule, we finalized the CQMs from which EPs would report beginning in CY 2014 under the EHR Incentive Program (77 FR 54069, Table 8). These CQMs are electronically specified and updated annually to account for issues such as changes in billing and diagnosis codes. The requirements specified in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 allow for the reporting of different versions of the CQMs. However, it is not technically feasible for CMS to accept data that is electronically reported according to the specifications of the older versions of the CQMs, including versions that may be allowed for reporting under the EHR Incentive Program. We stated in the EHR Incentive Program Stage 2 final rule that, consistent with section 1848(o)(2)(B)(ii) of the Act, in the event that the Secretary does not have the capacity to receive CQM data electronically, EPs may continue to report CQM data through attestation (77 FR 54076). Therefore, we proposed that EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. For example, for the reporting periods in 2014, EPs who want to report CQM data electronically for purposes of satisfying the quality measure reporting component of meaningful use would be required to use the June 2013 version of the CQMs electronic specifications (available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*) and ensure that their CEHRT has been tested and certified to the June 2013 version of the CQMs for purposes of achieving the CQM component of meaningful use in 2014. EPs who do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) would be allowed to report CQM data to CMS by attestation for the Medicare EHR Incentive Program.

We invited and received public comments on these proposals:

Comment: Some commenters supported our proposal to allow EPs to report on older versions of the CQM electronic specifications to CMS by attestation for the Medicare EHR Incentive Program.

Response: We appreciate the commenters' support for this proposal.

Comment: Some commenters recommended that, in lieu of requiring that all EPs report the most recent version of the electronic specifications for the CQMs and attest to older versions of the electronic specifications for the CQMs, CMS work with ONC to revise the current development and implementation timeline to ensure one set of measure specifications for all EPs.

Response: In the future, we hope to improve our development and implementation timelines so that all EPs would report on only one version of the CQMs. Unfortunately, at this time, it is not technically feasible for CMS to modify our development and implementation timelines to achieve this goal in 2014.

Comment: One commenter opposed our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs, as it creates unnecessary burden on EHR vendors.

Response: We appreciate the commenter's response. We respectfully disagree with the commenter's opposition to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. We believe it is important for EPs to electronically report the most recent versions of the electronic specifications for the CQMs as updated measure versions correct minor inaccuracies found in prior measure versions. To ensure that CEHRT products can successfully transmit CQM data using the most recent version of the electronic specifications for the CQMs, it is important that the product be tested and certified to the most recent version of the electronic specifications for the CQMs. As noted in the proposed rule, at this time, it is not technically feasible for CMS to accept more than one version of the electronic measure specifications for the CQMs. For these reasons, except for the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), we are not accepting older versions of the electronic specifications for the CQMs.

Comment: The majority of commenters supported our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. Some commenters had concerns regarding whether there would be sufficient time for EHR technology developers to update their systems and timely distribute the updated CQM versions in a way that would enable EPs to report

on the updated versions. A commenter stated that the 6-month release in June for implementation for reporting in the EHR Incentive Program beginning in January 1, 2014 may not provide enough time for CEHRT systems to be updated. Therefore, the commenter requested that any updates made to measure specifications be minimal. Any major changes to the measure itself, the measure logic, or the value sets would require additional time to address all necessary steps in the implementation process, and should be avoided.

Response: We understand the commenter's concerns regarding the implementation timeline. We agree that any changes to the electronic specifications for the CQMs should be non-substantive. Indeed, please note that, as we noted in the EHR Incentive Program Stage 2 final rule, any substantive changes that will be made to the CQM electronic measure specifications will be non-substantive (77 FR 54055–54056).

Therefore, after consideration of the comments received and for the reasons stated previously, we are finalizing the following proposal: EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs.

We are also finalizing the policy that EPs who do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) will be allowed to report CQM data to CMS by attestation for the Medicare EHR Incentive Program. For further explanation of reporting CQMs by attestation, we refer readers to the EHR Incentive Program Stage 1 final rule (77 FR 44430 through 44434) and the EHR Incentive Program's Registration and Attestation page (available at *https://ehrincentives.cms.gov/hitech/login.action*). Please note that for attestation we are not requiring that products reporting on older versions of the electronic specifications for the CQMs have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. Rather, if attesting to older versions of the electronic specifications for the CQMs, it is sufficient that the product is CEHRT certified to the 2014 Edition certification criteria.

For the reporting periods in 2014, EPs who want to report CQM data electronically (through a qualified clinical data registry or other product that is CEHRT) to satisfy the quality measure reporting component of meaningful use must use the June 2013 version of the CQMs electronic specifications (available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*). CQM data must be submitted using either the QRDA–I or QRDA–III format as finalized in the Stage 2 final rule (77 FR 54076). In addition, EPs must ensure that their CEHRT has been tested and certified to the June 2013 version of the CQMs for purposes of achieving the CQM component of meaningful use in 2014. Please note that, for 2014 only, we are providing one exception to this rule for the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387) because an error was found in the June 2013 logic of this measure. The June 2013 version of this measure was posted on CMS's Web site on June 29, 2013. The error relates to the relative timing of the diagnosis of breast cancer and the diagnosis of ER or PR positive breast cancer. In clinical practice, a diagnosis of breast cancer should precede the more specific diagnosis of ER or PR positive breast cancer. The logic in CMS140v2 reverses this order. The expected impact of this error is that very few but most likely no patients will meet the denominator criteria. Therefore, if EPs want to report this measure electronically, we are requiring that EPs report on the measure CMS140v1, which is the prior, December 2012 version of the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387). To the extent that an EP reports another version of this measure other than CMS140v1, (for example, if their certified EHR technology includes the other version), we require EPs to report the other version by attestation. Should an EP report on CMS140v2, the June 2013 version of the measure titled Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), the EP must report this June 2013 version of the measure by attestation.

4. Reporting Periods in CY 2014

In the Stage 2 final rule, we established the EHR reporting periods in CY 2014 for EPs that have previously demonstrated meaningful use (77 FR 53975). Specifically, we finalized a three-month CY quarter EHR reporting period for 2014, which means that Medicare EPs will attest using an EHR reporting period of January 1, 2014 through March 31, 2014; April 1, 2014 through June 30, 2014; July 1, 2014 through September 30, 2014; or October 1, 2014 through December 31, 2014. We also established the reporting periods for CQMs in CY 2014, which are generally the same as the EHR reporting period (77 FR 54049–54051). Although we did not propose to change these established reporting periods, we understand that there may be instances where an EP may prefer to report CQM data for a certain quarter and report the meaningful use objectives and measures for a different quarter. For example, a technical problem could arise for a submission of CQM data that would not affect an EP's submission of meaningful use functional measures, or vice versa. To provide additional flexibility for EPs, we will accept reporting periods of different quarters for CQMs and for meaningful use functional measures, as long as the quarters are within CY 2014. We note that if an EP chooses to use a reporting option for the Medicare EHR Incentive Program that aligns with another CMS quality reporting program, the EP should be mindful of the reporting period required by that program if the EP seeks to meet the quality measure reporting requirements for both the Medicare EHR Incentive Program and the aligned quality reporting program.

J. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in healthcare costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

ACOs are required to completely and accurately report on all quality performance measures for all quality measurement reporting periods in each performance year of their agreement period. There are currently 33 quality performance measures under the Shared

Savings Program. For Shared Savings Program ACOs beginning their agreement period in April or July, 2012, there will be two reporting periods in the first performance year, corresponding to calendar years 2012 and 2013. For ACOs beginning their agreement periods in 2013 or later, both the performance year and reporting period will correspond to the calendar year. Reporting on measures associated with a reporting period will generally be done in the spring of the following calendar year. For example, an ACO will submit quality measures for the 2015 reporting period in early 2016.

1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment

Section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''. . . incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 . . .'' and permits the Secretary to ''use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we incorporated certain Physician Quality Reporting System (PQRS) reporting requirements and incentive payments into the Shared Savings Program, including: (1) the 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889 through 67890); (2) reporting via the GPRO web interface; (3) criteria for satisfactory reporting; and (4) set January 1 through December 31 as the reporting period. The regulation governing the incorporation of PQRS incentives and reporting requirements under the Shared Savings Program is set forth at § 425.504.

Under section 1848(a)(8) of the Act, a payment adjustment will apply under the PQRS beginning in 2015 based on quality reporting during the applicable reporting period. Eligible professionals who do not satisfactorily report quality data in 2013 will be subject to a downward payment adjustment applied to the PFS amount for covered professional services furnished by the eligible professional during 2015. For eligible professionals subject to the 2015 PQRS payment adjustment, the fee schedule amount is equal to 98.5 percent (and 98 percent for 2016 and each subsequent year) of the fee schedule amount that would otherwise apply to such services. To continue to align Shared Savings Program requirements with PQRS, for the 2013 reporting period (which will be used to determine the 2015 PQRS payment adjustment to PFS amounts), in the CY 2013 PFS final rule with comment (77 FR 69372), we amended § 425.504 to include the PQRS reporting requirements necessary for eligible professionals in an ACO to avoid the 2015 PQRS payment adjustment. Specifically, we required ACOs on behalf of eligible professionals that are ACO providers/suppliers to successfully report one ACO GPRO measure in 2013 to avoid the payment adjustment in 2015. We also provided that ACO providers/suppliers that are eligible professionals may only participate under their ACO participant tax identification number (TIN) as a group practice for purposes of avoiding the PQRS payment adjustment in 2015. Thus, ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as individuals under the traditional PQRS or under the traditional PQRS GPRO under their ACO participant TIN. We note, however, that eligible professionals may bill Medicare under more than one TIN (for example, eligible professionals may bill Medicare under a non-ACO participant TIN in one practice location and also bill Medicare under the TIN of an ACO participant at another practice location). As a result, ACO providers/suppliers who are eligible professionals that bill under a non-ACO participant TIN during the year could and should participate under the traditional PQRS as either individual EPs or a group practice for purposes of avoiding the PQRS payment adjustment for the claims billed under the non-ACO participant TIN. In fact, such EPs would have to do so to avoid the PQRS payment adjustment with respect to those claims because the regulation at § 425.504 only applies to claims submitted by ACO providers/suppliers that are eligible professionals billing under an ACO participant TIN. If eligible professionals within an ACO meet the requirements for avoiding the PQRS payment adjustment established under the Shared Savings Program, only the claims billed through the TIN of the ACO participant will avoid the payment adjustment in 2015.

For the 2014 reporting period and subsequent reporting periods (which would apply to the PQRS payment adjustment for 2016 and subsequent payment years), we proposed to align with the requirements for reporting under the traditional PQRS GPRO through the CMS web interface by amending § 425.504 to require that ACOs on behalf of their ACO providers/suppliers who are eligible professionals satisfactorily report the 22 ACO GPRO measures during the 2014 and subsequent reporting periods to avoid the PQRS payment adjustment for 2016 and subsequent payment years (78 FR 43482). Additionally, we proposed to continue the current requirement that ACO providers/suppliers who are eligible professionals may only participate under their ACO participant TIN for purposes of the payment adjustment in 2016 and subsequent years.

As we stated in the proposed rule (78 FR 43482), we believe that the proposal to modify the requirements for ACOs to satisfactorily report the 22 ACO GPRO measures to avoid the 2016 payment adjustments would not increase burden on ACOs or on ACO providers/suppliers that are eligible professionals because ACOs must already report these measures in order to satisfy the Shared Savings Program quality performance standard. Thus, this proposal would not increase the total number of measures that must be reported by the ACO and its ACO providers/suppliers that are eligible professionals. We also noted that these proposals would not affect the Shared Savings Program quality performance standard reporting requirement under which ACOs are currently required to report on 33 quality performance measures, which includes all 22 of the ACO GPRO quality measures.

Comment: We received several comments in favor of continued alignment with PQRS reporting requirements and ongoing efforts to harmonize the program. We received no comments against continued alignment. One commenter said alignment minimizes the additional reporting burden on ACOs and is consistent with ongoing quality initiatives. Another commenter said alignment between programs eases administrative burden. In addition we received some comments about the Pioneer ACO Model's alignment with PQRS that are out of the scope of this proposed rule. We have shared these comments with our colleagues in the Innovation Center. In addition, two commenters stated that when a physician leaves an ACO, the ACO should not be responsible for reporting quality measures for that physician.

Response: We appreciate the comments in support of our proposal, and for the reasons discussed above and in the proposed rule, we are finalizing our proposal to align with PQRS GPRO

web interface reporting requirements, finalized elsewhere in this PFS, for eligible professionals (EPs) and their participant TINs in ACOs to avoid the payment adjustment in 2016 and subsequent years. We are also finalizing our proposal to add a new paragraph (c) to the regulation at § 425.504 to reflect these reporting requirements for 2016 and subsequent years. Although we are finalizing this policy as proposed, we have made some technical corrections to the text and formatting of § 425.504(c) in order to remove inconsistent language that was inadvertently included in this provision as it appeared in the proposed rule. With respect to the comments about changes in the ACO participants and ACO providers/suppliers and the effect on ACO quality reporting, these issues are out of the scope of this rule. We note, however, that we have addressed the effect of changes in ACO participants on ACO quality reporting in subregulatory guidance available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html.* Additionally, ACOs are required to report certain measures using the GPRO web interface tool. Specifically, § 425.504(a)(1) and (b)(1) require that ACOs submit quality measures using the GPRO web interface to qualify on behalf of their eligible professionals for the PQRS incentive or to avoid the PQRS payment adjustment. This reporting mechanism is also referenced in § 425.308(e), which provides that quality measures that ACOs report using the GPRO web interface will be reported by CMS on the Physician Compare Web site.

Under § 414.90(h)(3)(i), group practices may report data under the traditional PQRS GPRO through a CMS web interface. The Shared Savings Program regulations at § 425.504(a)(1) and (b)(1) and § 425.308(e) specifically reference the use of the GPRO web interface for quality reporting purposes. We proposed to amend these regulations to replace references to GPRO web interface with CMS web interface. We believe this change will ensure consistency with the reporting mechanism used under § 414.90(h)(3)(i) and will also allow for the flexibility to use a similar web interface in the event that operational issues are encountered with the use of the GPRO web interface. We invited public comment on this proposal.

Comment: We did not receive direct comments against broadening our reference to the web interface; however, one commenter expressed concern that the suggested change signaled that CMS intends to change the reporting mechanism and the commenter opposed any change in reporting mechanism saying, it took time and resources to learn the current reporting mechanism.

Response: We are finalizing our proposal to use the more broad term CMS web interface to align with PQRS, and are also finalizing the proposed revisions to our regulations at §§ 425.308(e) and 425.504(a)(1) and (b)(1) to reflect this change. We would like to reassure Shared Saving Program ACOs that we do not currently have plans to change the reporting mechanism for Shared Savings Program ACOs from the GPRO web interface. However, broadening the term to ''CMS web interface'' aligns with PQRS and gives CMS the flexibility to use an alternative web interface in the event that PQRS requirements change or operational issues with the GPRO web interface adversely impact ACO quality reporting.

We also received a comment making suggestions about the reporting mechanism used under the Pioneer ACO Model. This comment is out of the scope of the proposed rule, but we have shared the comment with our colleagues in the Innovation Center.

2. Medicare Shared Savings Program-Establishing the Quality Performance Benchmark

Section 1899(b)(3)(C) of the Act directs the Secretary to ''. . . establish quality performance standards to assess the quality of care furnished by ACOs . . .'' and to ''improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care.'' In the Shared Savings Program final rule, we finalized the following requirements with regard to establishing a performance benchmark for measures: (1) During the first performance year for an ACO, the quality performance standard is set at the level of complete and accurate reporting; (2) during subsequent performance years, the quality performance standard will be phased in such that ACOs will be assessed on their performance on each measure; (3) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures; and (4) contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national Medicare Advantage (MA) quality measure rates, or a national flat percentage. In the final rule, we indicated that we would not compare an ACO's quality performance to the performance of other ACOs for purposes of determining an ACO's overall quality score. We acknowledged, however, that in future program years, we should seek to incorporate actual ACO performance on quality measures into the quality benchmarks after seeking industry input through rulemaking.

a. Data Sources Used To Establish Performance Benchmarks

The regulation governing the data that CMS will use to establish the performance benchmarks for quality performance measures under the Shared Savings Program is set forth at § 425.502(b)(2). This provision states that CMS will define the performance benchmarks based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage. In the Shared Savings Program final rule, we responded to comments suggesting that quality performance benchmarks be set based on actual historical data submitted by ACOs. We stated that although we agreed that we should seek to incorporate actual ACO performance on quality scores into the quality benchmark, we would do so only in future rulemaking so that we could seek industry input. In addition, we noted that we expected to update the quality benchmarks over time, consistent with section 1899(b)(3)(C) of the Act, which requires CMS to seek to improve the quality of care furnished by ACOs participating in the Shared Savings Program over time.

Consistent with our stated intention to incorporate actual ACO experience into quality measure benchmarks, for the 2014 reporting period, we proposed to amend § 425.502(b)(2) to permit CMS to use all available and applicable national Medicare Advantage and Medicare FFS performance data to set the quality performance benchmarks. Specifically, in addition to using available national Medicare FFS rates, which include data reported through PQRS, and national MA quality measure rates, we proposed to use data submitted by Shared Savings Program and Pioneer ACOs in 2013 for the 2012 reporting period to set the performance benchmarks for the 2014 reporting period. We proposed to publish the quality benchmarks based upon these data prior to the beginning of the 2014 reporting period through subregulatory guidance. As stated in the Shared Savings Program final rule, we establish benchmarks using the most currently available data source and the most recent available year of benchmark data prior to the start of the reporting period. In other words, data collected in 2014

from the 2013 reporting period would be used in conjunction with other available data to set benchmarks for the 2015 reporting period, and so on. We proposed to retain the option of using flat percentages when data are unavailable, inadequate or unreliable to set quality performance benchmarks. Further, we clarified our intent to combine data derived from national Medicare Advantage and national Medicare FFS to set performance benchmarks when the measure specifications used under Medicare Advantage and FFS Medicare are the same. We proposed to revise § 425.502(b)(2)(i) to reflect this clarification. We solicited comment on these proposals, and whether there are other data sources that should be considered in setting performance benchmarks.

Comment: We received a generally favorable response to incorporating ACO data into setting the benchmarks, and a few commenters supported using all available data, including ACO data, to establish benchmarks; one commenter in favor of using all data stated more data are better for setting benchmarks, and including ACO data emphasizes that CMS expects all providers to improve quality. However, most commenters opposed the proposal to use ACO data alone when no other data were available to set benchmarks, stating that they believed that when only ACO data were available it would unfairly narrow the data set. They stated that ACOs should be assessed against the broader FFS population instead of only against themselves. A few commenters stated that culture and the socioeconomic status of some patient populations could adversely affect scoring for these organizations if they were compared only to other ACOs, particularly on the CAHPS measures, and that each community and its resources and characteristics should be taken into account when establishing benchmarks, including rewarding ACOs on the basis of individual improvement. Similarly, other commenters felt that using ACO data alone would inflate the benchmarks and make them unattainable to new ACOs entering into the program the following year. A few commenters suggested that CMS not move to pay for performance, but rather continue pay for reporting when there are only ACO data available to set the benchmark. One commenter stated ''Among [Pioneer] ACOs, some metrics had a wide variation of interpretation that resulted in a bimodal distribution. When there is such a bimodal distribution, separate benchmarks should be used based on [ACO] interpretation [of the measure]—higher benchmarks for wide interpretation, lower benchmarks for stricter interpretation. . . . We recommend that benchmarks be based only on the subset of data consistent with the [ACO] interpretation that was chosen.'' When data other than ACO data are available, many commenters were opposed to combining it with MA data, stating that the structure of the MA program, with closed networks and the opt-in of beneficiaries, enables MA plans to attain higher performance scores. Some commenters also stated it was not fair to include PQRS GPRO data in developing quality performance benchmarks for ACOs because groups reporting under the PQRS GPRO are more advanced or integrated organizations that have multiple years of experience in collecting and reporting medical record data.

On the other hand, regarding use of flat percentages, one of the commenters said flat percentages should never be used. Another commenter suggested that flat percentages should only be used if the 60th percentile had a value of 70 percent or greater, particularly in relation to measures that are clustered. A commenter suggested starting with a flat percentage that is lower than actual ACO data, and then increasing the benchmark as more data become available in order to measure and reward ACO improvement over time.

Regarding our proposal to set benchmarks yearly based on the previous year's ACO reporting, a commenter expressed concern about fluctuating benchmarks in the event that CMS finalized its proposal to set benchmarks yearly based on the previous year's ACO data submission. Commenters noted that such a policy may unfairly disadvantage ACOs joining the program, particularly when only ACO data are available to set benchmarks.

Response: We are finalizing our proposal to use fee-for-service data, including data submitted by Shared Savings Program and Pioneer ACOs to set the performance benchmarks for the 2014 and subsequent reporting periods. Although we continue to believe it is appropriate to combine data from MA and PQRS reporting when the quality measure specifications are the same, or to use MA data when FFS data are unavailable, we are swayed by commenters who request that in light of the different structure of the MA program, we reconsider using MA data to set benchmarks in the early stages of the program. Therefore, we will not finalize our proposal to use MA data alone or in combination with fee-for-service data in the short-term. We intend to revisit the policy of using MA data in future rulemaking when we have more experience setting benchmarks for ACOs. However, we are finalizing our proposal to combine all available Medicare fee-for-service quality data, including data gathered under PQRS (through both the GPRO tool and other quality reporting mechanisms). We continue to believe that it is appropriate to use PQRS GPRO data to set benchmarks because the measure specifications are the same and are submitted by FFS providers. We do not agree with commenters who suggested that PQRS GPROs have an unfair advantage over other providers because PQRS GPROs range in size and capability. Nor do we agree with commenters that recommended setting benchmarks that take into consideration ACO interpretation of measure specifications. The GPRO web interface and measure specifications, as well as education on how to report the measures, are equally available to all Medicare enrolled providers, and the measure specifications are not subject to ACO interpretation.

Finally, we recognize the concerns raised by commenters that setting benchmarks based on ACO data alone, particularly in the early years of the Shared Savings Program, could result in punishing relatively high performers for quality measures where performance is high among most ACOs. Additionally, we appreciate the suggestions by commenters who incorporated our proposed de-clustering methodology on when and how to use flat percentages to reward high performance. We are finalizing an approach that makes use of a combination of actual data and flat percentages; specifically, we will use all available FFS data to calculate benchmarks, including ACO data, except where performance at the 60th percentile is equal to or greater than 80 percent for individual measures, regardless of whether or not the measure is clustered. In these cases, a flat percentage will be used to set the benchmark for the measure. By way of example, please refer to Table 81. This policy allows ACOs with high scores to earn maximum or near maximum quality points while allowing room for improvement and rewarding that improvement in subsequent years. We chose 80 percent because this level of attainment indicates a high level of performance and we believe ACOs achieving an 80 percent performance rate should not be penalized as low performers.

TABLE 81—METHODOLOGY FOR SETTING BENCHMARKS USING FLAT PERCENTAGES

Percentile	30th	40th	50th	60th	70th	80th	90th
Performance rates using all available FFS data	85.83	86.21	86.76	87.15	87.65	88.21	89.23
Revised benchmark using flat percentages when the 60th percentile is 80 percent or more.	30.00	40.00	50.00	60.00	70.00	80.00	90.00
Quality points earned by the ACO**	1.10	1.25	1.40	1.55	1.70	1.85	2.0

Example is for illustration purposes only and is not based on actual data.
** Note: Points are double the points shown here for the EHR measure.

We are also finalizing our proposal to set benchmarks prior to the reporting year for which they would apply. Specifically, we are finalizing our proposal to set the quality performance benchmarks for the 2014 reporting period using data submitted in 2013 for the 2012 reporting period. We will publish the quality performance benchmarks for the 2014 reporting period through subregulatory guidance. However, we are not finalizing our proposal to modify the benchmarks on a yearly basis. We recognize commenters' concerns that for some measures in the first few years, we will only have a limited amount of data which may cause benchmarks to fluctuate in early program years, making it difficult for ACOs to improve upon their previous year's performance. Instead, we will set the benchmarks for the 2014 reporting year in advance using data submitted in 2013 for the 2012 reporting year, and continue to use those benchmarks for 2 reporting years (specifically, the 2014 and 2015 reporting years). We intend to readdress this issue in future rulemaking to allow for public comment on the appropriate number of years before updating benchmarks going forward. We have revised the regulation at § 425.502(b)(2) to reflect these final policies with respect to defining the quality benchmarks.

b. Ensuring Meaningful Differences in Performance Rates

Data collected by CMS from the GPRO and Physician Group Practice Demonstration participants in 2012 coupled with previous CMS experience indicates that using actual data to calculate quality performance may result in some measures' performance rates being tightly clustered. In this case, quality scores for the measure may not reflect clinically meaningful differences between the performance rates achieved by reporters of quality. For example, for some measures, the distribution of performance rates may have a spread of less than 2.0 percentage points between the 30th and 90th percentiles. In such an instance, even though there is little distinction in actual performance rates, a slight difference in performance on the measure may result in a significant difference in the number of quality points obtained under the Shared Savings Program. For example, two separate ACOs at the 50th percentile and the 90th percentile may have only a few tenths of a percentage point difference in their actual performance, but under the Shared Savings Program scoring methodology, the difference between their quality scores for that measure would be more noteworthy (1.4 points versus 2.0 points).

We continue to believe it is desirable to use performance rates for measures based on actual data because doing this creates benchmarks that are simple to understand and apply, even if the rates are clustered, as the data reflect achievable performance on quality measures. However, allowing clustered performance rates for a measure may result in payment differences that are not associated with clinically meaningful differences in patient care, as noted in the example above.

Keeping these issues in mind, we proposed to develop a methodology to spread clustered performance on measures. The first step in developing that methodology is to identify when performance on a measure is clustered. Clustering could be defined as less than a certain spread between performance rates in an identified range; for example, less than 6.0 percentage points between the performance rates associated with the 30th and 90th percentiles, or less than 10.0 percentage points between the minimum and maximum values achieved by previous reporters of the quality measure. Alternatively, clustering could be defined as a spread of performance rates of less than x percentage points between any two deciles, for example, less than a 1.0 percentage point difference between the 60th and 70th decile.

Once a clustered measure has been identified, the next step is to apply a methodology to spread or separate the performance rates within the measure. It is important to establish a meaningful performance rate, or starting point, around which to differentiate or spread the performance. For example, selecting a certain percentile or median value may represent one option for establishing a reasonable starting point. Once the starting point is set, then we could implement a series of fixed percentage point intervals around the starting point in both a positive and negative direction to increase the spread, for example, applying a fixed 1.0 percentage point interval between scored deciles. For example, if the starting point is the 60th percentile, and the performance rates at the 60th and 70th percentiles were observed to be 77.15 and 77.65 respectively, there would be only a 0.5 spread between the deciles. In contrast, applying a fixed 1.0 percentage point interval to increase spread would result in a 1.0 difference between these rates, and the new performance rates would be 77.15 and 78.15 at the 60th and 70th percentiles, respectively. In the alternative, we could take the spread calculated from a subset (for example, ACO performance only) of the underlying performance data if we believe that data reported by ACOs show a different variability than other data sources. For example, the spread between the measure's percentiles could be based on historical ACO distribution only, not the historical distribution of Medicare Advantage and/or national fee-for-service, PQRS, and ACO data. The historical ACO distribution could then be applied to the Medicare Advantage and/or national fee-for-service, PQRS, and ACO percentile distribution to establish the measure's percentiles.

In the proposed rule, we stated that we believe that a clinically meaningful assessment of ACO quality is important. We also noted that we are interested in providing a pathway for ACOs new to quality reporting to achieve the quality reporting standard, and an incentive for experienced ACOs to continue improving and performing at high levels. We therefore proposed to use a standardized method for calculating benchmark rates when a measure's performance rates are tightly clustered. We proposed that the application of a methodology to reduce measure clustering would only apply to quality

measures whose performance rates are calculated as percentiles, that is, the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe that measures whose performance rates are calculated as ratios already demonstrate a high degree of clinically meaningful differences because they are risk adjusted to reflect the health status of the patient population being measured.

We proposed to define a tightly clustered measure, including clinical process and outcome measures reported through the GPRO web interface and CAHPS measures, as one that demonstrates less than a 6.0 percentage point spread in performance rates between the 30th and 90th percentiles. As discussed in the proposed rule, we believe using the 30th and 90th percentiles as the lower and upper bounds is reasonable because these bounds have been given some significance in earlier rulemaking; specifically, the Shared Savings Program regulations set the ACO's minimum attainment level at the 30th percentile, below which the ACO achieves no points, and the ACO achieves full points for quality reporting at or above the 90th percentile. Further, we proposed to establish the starting point at the 60th percentile, the midpoint between the 30th and 90th percentiles, and then to apply a positive 1.0 fixed percentage point interval for each decile above the 60th percentile and a negative 1.0 fixed percentage point interval for each decile below the 60th percentile.

We recognized that spreading tightly clustered performance measures would decrease the lower bound necessary to meet the minimum attainment level for the measure, giving ACOs new to quality reporting a greater opportunity to meet the quality performance standard. At the same time, spreading tightly clustered performance rates would increase the upper bound necessary for achieving the maximum available quality points for the measure, giving already experienced ACOs an incentive to continue improving quality. Applying a 1.0 fixed percentage point interval achieves the goal of creating meaningful differences in performance. Further, we stated that we believe that applying a 1.0 fixed percentage point interval represents a tempered and reasonable interval that does not spread performance rates to levels that are too easy to achieve on the lower bound or too difficult to achieve on the upper bound.

For example, Table 82 demonstrates the original spread of a quality measure, based on all available data, which is compressed from a range of 75.83 at the 30th percentile to 79.23 at the 90th percentile, that is, a spread of less than 6.0 percentage points. When the proposed methodology is applied, the 60th percentile (or 77.15 percent), serving as the starting point, remains unchanged. The spread increases 6.0 percentage points from 74.15 at the 30th percentile to 80.15 at the 90th percentile. As demonstrated and explained above, this methodology improves the distinction in performance between the minimum attainment level (30th percentile) and the maximum attainment level (90th percentile).

TABLE 82—PROPOSED METHODOLOGY TO REDUCE CLUSTERED PERFORMANCE RATES

Percentile	30th	40th	50th	60th	70th	80th	90th
Original performance rates using all available data	75.83	76.21	76.76	77.15	77.65	78.21	79.23
Performance rates using methodology to reduce clustering	74.15	75.15	76.15	77.15	78.15	79.15	80.15

* Example is for illustration purposes only and is not based on actual data.

We proposed to amend § 425.502(b) to reflect this methodology to reduce clustering. We solicited comment on these proposals. Specifically, we sought comment on whether or not a methodology should be applied to spread out clustered performance on measures. We also solicited comment on the proposal to define clustered performance on a measure as one in which the spread of performance rates between the 30th and 90th percentiles is less than 6.0 percentage points, or whether other values should be used to define clustered measure performance, for example, when the minimum and maximum reported values are spread by less than 10.0 percentage points. We also solicited comment on whether there are alternative methodologies that should be considered to spread out clustered performance on measures. In addition, we solicited comment on whether measures that are calculated as ratios should be excluded from this methodology. We also requested comment on whether all available relevant data should be considered when developing the spread between measures, or whether only the relevant performance data from a subset of reporters, such as ACO-reported data, as discussed above, should be used to determine the appropriate spread between deciles.

Comment: We received many comments against creating a larger spread when quality measure benchmarks are clustered. No commenters were in favor of spreading benchmarks when they are clustered. Alternatives proposed by commenters were to continue pay for reporting when the scores are clustered, or to develop a methodology that rewards improvement in individual ACO quality scores and to structure points to reward ''positive outliers'' when scores are clustered at the lower scores. A commenter said, ''While there may not be a significant spread for comparison, those entities that do perform at a relatively close level of quality performance should be recognized for their actual level of performance.'' A commenter suggested considering approaches that are not threshold- and benchmark-based, but instead reward every single instance when correct care was provided. Another commenter suggested using fewer points of differentiation such as quartile scores rather than decile scores for clustered measures. A commenter suggested CMS adopt a methodology that rewards all the good performing programs and further rewards the excellent ''best practices.'' A commenter suggested using a flat percentage if the 60th percentile value is above an absolute rate of 70 percent as an alternate approach to addressing tightly clustered measures.

Response: We appreciate the comments and suggestions for alternatives for addressing tightly clustered measures. We are not finalizing the proposal to create a spread when benchmarks are tightly clustered. We are convinced by commenters who said that spreading benchmarks could create artificial clinically meaningful differences in quality reporting and payment, particularly when underlying performance relative to peers would remain unchanged. However, we reserve the right to revisit this issue in future

rulemaking when we have more experience and data.

Instead, we will use the method described above which will take into account actual ACO performance on measures by using FFS data (including ACO and PQRS reported data) where available to set benchmarks except where performance at the 60th percentile is equal to or greater than 80 percent, in which case, flat percentages will be used to set the benchmark. We chose this threshold for the reasons noted above. This method will both reduce clustering for these measures and reward ACOs for actual performance. Additionally, as we move toward using ACO data to set benchmarks, we will continue to consider how clustering of measures intersects with our ability to determine both an appropriate minimum standard for a quality measure as well as how the overall performance on that measure is scored for the ACO, or whether these concepts should be decoupled.

Finally, in response to comments on alternative explicit ways to reward improvement, we note that the Shared Savings Program methodology rewards organizations with a greater share of savings for higher quality performance in pay for performance years; however, we will continue to consider this issue and may address it further in future rulemaking.

c. Scoring CAHPS Measures Within the Patient Experience of Care Domain

The preamble to the Shared Savings Program final rule (76 FR 67895–67900) outlines the total potential points available per domain as demonstrated in Table 83. As indicated in Table 83, under the final rule the Patient/Caregiver Experience Domain is weighted equally with the other three quality domains at 25 percent and consists of 2 measures: A composite of six Clinician and Group (CG) CAHPS summary survey measures (1) Getting Timely Care, Appointments and Information, (2) How Well Your Doctors Communicate, (3) Patient's Rating of Doctor, (4) Access to Specialists, (5) Health Promotion and Education, (6) Shared Decision Making, and a Health Status/Functional Status measure. The six measures included in the composite will transition to pay-for-performance starting in the second year of an ACO's agreement period. In contrast, the Health Status/Functional Status measure will remain pay-for-reporting throughout the ACO's entire agreement period.

TABLE 83—TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (in percent)
Patient/Caregiver Experience	7	1 measure, with 6 survey module measures combined, plus 1 individual measure.	4	25
Care Coordination/Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points) ..	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	23	48	100

* From Table 4 in the Shared Savings Program Final Rule (76 FR 67899).

The result of this point system is that performance on the six patient experience measures is worth only 12.5 percent of an ACO's total performance score because the other 12.5 percent of the Patient/Caregiver Experience domain is the Health Status/Functional Status measure, which is a pay-for-reporting measure for all performance years. However, as we stated in the proposed rule, we believe that each of these seven measures is equally important within the Patient/Caregiver Experience domain, and that scoring within the domain should better reflect performance on these measures, thereby placing a greater emphasis on the voice of the patient through patient-reported outcomes and experiences. We believe that increasing the weight of the 6 measures that will become pay-for-performance in the second year of the agreement period will incentivize ACOs to improve their performance on these measures. A policy to place a greater emphasis on patient-reported outcomes and experiences is consistent with our goal to improve the quality of care furnished by ACOs over time.

Therefore, we proposed to modify the point scoring for the Patient/Caregiver Experience domain as demonstrated in Table 84. As modified, each of the 7 survey module measures within the domain would be assigned a maximum value of 2 points. The Patient/Caregiver Experience domain would then be worth a total of 14 points, rather than 4 points. The end result would be that each of the 7 measure modules in the domain would have equal weight. We noted that this change would not affect the weighting of the domain itself in relationship to the other three domains; it would remain 25 percent of the ACO's total quality performance score.

TABLE 84—MODIFIED TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (in percent)
Patient/Caregiver Experience	7	7 individual survey module measures	14	25
Care Coordination/Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points) ..	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25

TABLE 84—MODIFIED TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD—Continued

Domain	Total individual measures (table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (in percent)
Total	33	28	58	100

We stated that we believe giving equal weight to each of the Patient/Caregiver Experience measures modules is appropriate because it places greater emphasis on patient-reported experiences, promotes clinically meaningful differences in ACO performance within the domain, and is consistent with the statutory mandate to improve quality of care furnished by ACOs over time. The proposed change would also bring the total points for the domain in line with the points available in other domains.

We solicited comments on our proposal to modify the point scoring within the Patient/Caregiver Experience domain.

Comment: A majority of comments received were in support of reweighting the CAHPS measure modules. Commenters stated that assigning each measure module equal weight would be consistent with the patient centric goals of the ACO program. We received two comments against reweighting before the end of the first ACO agreement period. These commenters stated that the weighting should remain as it is to allow ACOs to ''cement this capability.'' Finally, a commenter made the comment that the CAHPS data is not timely or actionable.

Response: We appreciate the comments in support of reweighting the CAHPS measure module scoring and, for the reasons discussed above and in the proposed rule, are finalizing our proposal to assign 2 points to each of the 6 CAHPS survey measure modules (12 points) instead of scoring them as one component worth only two points. Reweighting will take effect for the 2014 reporting period for all Shared Savings Program ACOs and will increase the value of the patient experience of care domain from 4 points to 14 points and result in the six survey measure module in the patient experience of care survey accounting for 86 percent of the domain score. We note that the overall domain's weight would remain the same in relation to the other three domains, and therefore do not believe this reweighting will impact an ACO's ability to 'cement' its capabilities. Finally, we disagree that the information gathered from the patient experience of care survey is not actionable. The survey results, in conjunction with information derived from the ACO's process to promote internal cost and quality reporting, as required under the Shared Savings Program regulations, can be used by ACOs to identify areas for improvement, monitor care for its patient population, and improve, as well as measure the ACO's performance in this domain.

K. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the value-based payment modifier to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the value-based payment modifier to be budget neutral.

In this final rule with comment period, we are finalizing our proposed policies to continue to phase in implementation of the value-based payment modifier by applying it to smaller groups of physicians and to increase the amount of payment at risk. We also are finalizing our proposals to refine the methodologies used in our quality-tiering approach to calculating the value-based payment modifier in order to better identify both high and low performers for upward and downward payment adjustments. We note two changes from our proposals that we are finalizing after considering the public comments we received. First, we are adopting a single plurality attribution approach for the Medicare Spending per Beneficiary cost measure rather than the proposed multiple attribution approach. Second, we are adopting a threshold of 50 percent (rather than the proposed 70 percent) for the percentage of individual eligible professionals in a group of physicians that must meet the criteria to avoid the CY 2016 PQRS payment adjustment in order to calculate a group quality score.

2. Governing Principles for Physician Value-Based Payment Modifier Implementation

In the CY 2013 PFS final rule with comment period (77 FR 69306), we stated that the value-based payment modifier has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and more effective healthcare by providing upward payment adjustments under the PFS to high performing physicians (and groups of physicians) and downward adjustments for low performing physicians (and groups of physicians). We also noted that Medicare is implementing value-based payment adjustments for other types of services, including inpatient hospital services. Further, in implementing value-based purchasing initiatives generally, we seek to recognize and reward high quality care and quality improvements, and to promote more efficient and effective care through the use of evidence-based measures, the reduction in administrative burden and duplication, and less fragmented care.

In the CY 2013 PFS final rule with comment period, we established that the following specific principles should govern the implementation of the value-based payment modifier (77 FR 69307).

- *A focus on measurement and alignment.* Measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups, reflect the diversity of services furnished, and be consistent with the National Quality Strategy and other CMS quality initiatives, including the PQRS, the Medicare Shared Savings Program, and the Medicare EHR Incentive Program.
- *A focus on physician choice.* Physicians should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting physicians' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs.
- *A focus on shared accountability.* The value-based payment modifier can facilitate shared accountability by assessing performance at the group

practice level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician.

• *A focus on actionable information.* The Quality and Resource Use Reports (QRURs) should provide meaningful and actionable information to help groups of physicians and physicians identify clinical areas where they are doing well, as well as areas in which performance could be improved by providing groups of physicians with QRURs on the quality and cost of care they furnish to their patients.

• *A focus on a gradual implementation.* The value-based payment modifier should focus initially on identifying high and low performing groups of physicians. Moreover, groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in CY 2015. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed, refine physician peer groups, create finer payment distinctions, and provide greater payment incentives for high performance.

3. Overview of Existing Policies for the Physician Value-Based Payment Modifier

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the value-based payment modifier by applying it starting January 1, 2015 to payments under the Medicare PFS for physicians in groups of 100 or more eligible professionals. A summary of the existing policies that we finalized for the CY 2015 value-based payment modifier can be found in the proposed rule (78 FR 43486 through 43488).

4. Provisions of This Final Rule With Comment Period

We proposed additions and refinements to the existing value-based payment modifier policies. Specifically, the proposed rule included the following proposals:

• To apply the value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016.

• To make quality-tiering mandatory for groups within Category 1 for the CY 2016 value-based payment modifier, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology, and groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments determined under the quality-tiering methodology.

• To increase the amount of payment at risk under the value-based payment modifier from 1.0 percent to 2.0 percent in CY 2016.

• To align the quality measures and quality reporting mechanisms for the value-based payment modifier with those available to groups of physicians under the PQRS during the CY 2014 performance period.

• To include the Medicare Spending Per Beneficiary (MSPB) measure in the total per capita costs for all attributed beneficiaries domain of the cost composite.

• To refine the cost measure benchmarking methodology to account for the specialties of the physicians in the group.

In this final rule with comment period, we discuss each of the proposed policies, the comments received, our responses to the comments, and a brief statement of our final policy.

a. Group Size

In the CY 2013 PFS final rule with comment period, we stated that we would gradually phase in the value-based payment modifier in CY 2015 by first applying it to large groups (77 FR 69308), which we defined as groups of physicians with 100 or more eligible professionals. We noted our view that it would be reasonable to focus on groups with 100 or more eligible professionals before expanding the application of the value-based payment modifier to more groups and solo practitioners in CY 2016 and beyond.

To continue our phase-in of the value-based payment modifier, we proposed to apply the value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals. We estimated that this proposal would apply to approximately 17,000 groups (TINs) and nearly 60 percent of physicians under the value-based payment modifier in CY 2016. We believed this proposal would continue our policy to phase in the value-based payment modifier by ensuring that the majority of physicians are covered in CY 2016 before it applies to all physicians in CY 2017. Given the results of the statistical reliability analyses on the PQRS quality measures and the cost measures contained in the 2010 and 2011 groups and individual QRURs (78 FR 43500 through 43502), we stated that we believed we can reliably apply a value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016 and to smaller groups and to solo practitioners in future years. Accordingly, we proposed to revise the regulations at § 414.1210 to reflect that the CY 2016 value-based payment modifier would be applicable to physicians that are in groups with 10 or more eligible professionals. We solicited comments on this proposal.

The following is a summary of the comments we received regarding this proposal.

Comment: Several commenters supported our proposal to apply the value-based payment modifier to groups of 10 or more eligible professionals in 2016. Some commenters indicated that the proposed phased approach for increasing the number of physicians to which the value-based payment modifier applies was appropriate since the statute requires that the value-based payment modifier apply to all physicians in 2017.

Many commenters were opposed to our proposed policy. Some of these commenters stated that broadening the implementation of the value-based payment modifier to groups of 10 or more eligible professionals so quickly is premature because CMS did not have the opportunity to assess the impact on smaller groups, while others stated that implementation of the value-based payment modifier should be delayed until CMS can assure the accuracy and consistency of performance scoring. Some commenters were concerned about whether the groups that are currently subject to the value-based payment modifier have enough Medicare patients to ensure that cost and quality variation is truly measuring differences in performance rather than random risks. Commenters also noted that more than 10,500 groups will be 8 or 9 months into their first performance year before they see one of the confidential QRURs that are the key to CMS' value-based payment modifier outreach and education campaign. Other commenters suggested that there were too few subspecialist measures in the PQRS and that it would mean that small to mid-size groups would not have sufficient measures to be successful in the PQRS. Other commenters stated that groups of physicians with between 10 and 24 EPs would not have a QRUR until the summer of 2014 and thus should not be subject to the value-based payment modifier. Some commenters indicated that the value-based payment modifier is yet another regulatory burden as they transition to ICD–10. Still other comments objected to the entire concept of the value-based payment modifier and urged us not to implement it. Several commenters suggested that we apply the value-based payment modifier to groups of 25 or more eligible

professionals or to groups of 50 or more eligible professionals.

Response: Our focus as we gradually implement the value-based payment modifier is to increase quality measurement, because without measurement we do not believe that we can have consistent and sustained quality of care improvements for Medicare FFS beneficiaries. Furthermore, our approach to apply the value-based payment modifier to groups of 10 or more EPs is consistent with our principle to focus on a gradual implementation of the value-based payment modifier. Therefore, we disagree with commenters' suggestions that we not finalize our proposal to apply the value-based payment modifier to groups of 10 or more EPs, or that we instead apply the value-based payment modifier to groups of 25 or more EPs or 50 or more EPs, because this would delay improving quality of care furnished by groups of 10 or more EPs to FFS beneficiaries. We also continue to believe that we can validly and reliably apply a value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016 because we will be basing the quality score on the measures selected, and reported on, by the group of physicians or the individual EPs in the group. In addition, as discussed below, we are including an additional cost measure in the value-based payment modifier (the Medicare Spending per Beneficiary measure) and are adjusting our cost comparison approach to consider the medical specialty composition of the group of physicians.

Moreover, based on an analysis of our CY 2012 QRURs that we made available to groups of 25 or more eligible professionals on September 16, 2013, the PQRS quality measures and the cost measures used for the value-based payment modifier have high average statistical reliability. High statistical reliability in this context means we would arrive at consistent results under similar conditions. Moreover, these findings corroborate the findings from our group and individual CY 2010 and 2011 QRURs (78 FR 43500 through 43502) that found high reliability among the measures used for the value-based payment modifier. We found that the PQRS quality measures, even those reported at the individual level, were reliable; therefore, we believe that the PQRS quality measures for groups of 10 or more EPs will also be reliable. Further, because we use a minimum case size of 20 in order for a quality or cost measure to be included in the quality of care or cost composites of the value-based payment modifier, we believe that the composites will not only be valid, but also statistically reliable. Therefore, we disagree with the commenters' concerns about the statistical reliability of the PQRS quality measure performance rates. Furthermore, we will continue to monitor the value-based payment modifier program and continue to examine the characteristic of those groups of physicians that could be subject to an upward or downward payment adjustment under our quality-tiering methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

In the CY 2012 QRURs, we attributed, on average, 3007 beneficiaries to groups of 25 or more EPs. Moreover, approximately 65 percent of primary care services received by attributed beneficiaries were rendered by physicians in the group. Therefore, we do not agree with commenters' concerns about whether groups subject to the value-based payment modifier have enough Medicare patients to ensure that the variation in cost and quality is measuring differences in performance rather than random risk. And, as noted above, we also use a minimum case size of 20 when including quality and cost measures in the quality of care and cost composites of the value-based payment modifier.

Several commenters expressed concern regarding the number of PQRS measures applicable to subspecialists and suggested that small to mid-size groups do not have a sufficient number of measures in the PQRS to report. For purposes of the value-based payment modifier, we will use the performance on those measures that are reported through the PQRS reporting mechanisms adopted for the value-based payment modifier, even if fewer than three measures are reported, to calculate a group of physicians' quality composite score so long as the group of physicians (or at least 50 percent of the EPs in the group, if reporting as individuals under the PQRS) meet the criteria to avoid the 2016 PQRS payment adjustment. As discussed above in section H.4, we are modifying some of the satisfactory critieria for the 2016 PQRS payment adjustment that we believe addresses this concern so that such physicians will not be adversely affected under the value-based payment modifier.

In response to the commenters who objected to applying the value-based payment modifier to groups of 10 or more eligible professionals because groups of 10–24 eligible professionals have not seen how they would fare under the value-based payment modifier because they will not have a QRUR until midway through the CY 2014 performance period, we note that in the late summer of 2014, we plan to disseminate QRURs based on CY 2013 data to all physicians (that is, TINs of any size). These QRURs will contain performance information on the quality and cost measures used to score the quality and cost composites of the value-based payment modifier and will show how all TINs would fare under the value-based payment modifier policies finalized in this final rule with comment period. Please note that as discussed in section III.K.4.b. below, we are also finalizing our proposed policy to hold harmless groups with 10–99 eligible professionals from any downward payment adjustments under quality-tiering in CY 2016, thus shielding these groups from any downward payment adjustments in 2016.

Comment: Several commenters recommended that CMS reconsider its decision to exclude Accountable Care Organizations (ACOs) from the value-based payment modifier. These commenters indicated that ACOs should have the opportunity to be rewarded for their practice to the extent these groups provide high quality and, low cost care. Commenters recommended that ACOs be permitted to optionally participate in the value-based payment modifier or that CMS should provide a plan for addressing how innovators participating in the Medicare ACO programs will be affected by the value-based payment modifier.

Response: We finalized in the CY 2013 PFS final rule with comment period (77 FR 69313) that we will not apply the value-based payment modifier in CY 2015 and CY 2016 to groups of physicians that are participating in the Medicare Shared Savings Program Accountable Care Organizations (ACOs), the testing of the Pioneer ACO model, the Comprehensive Primary Care Initiative, or other similar Innovation Center or CMS initiatives. From an operational perspective, we will apply this policy to any group of physicians that otherwise would be subject to the value-based payment modifier, if one or more physician(s) in the group participate(s) in one of these programs or initiatives during the relevant performance period (CY 2013 for the CY 2015 value-based payment modifier, and CY 2014 for the CY 2016 value-based payment modifier). We will take these comments into consideration as we develop proposals for the value-

based payment modifier and ACOs in future years.

After consideration of the comments received and for the reasons stated previously, we are finalizing that the value-based payment modifier will apply to groups of physicians with 10 or more eligible professionals in CY 2016.

We proposed to identify groups of physicians that would be subject to the value-based payment modifier (for example, for CY 2016, groups of physicians with 10 or more eligible professionals) using the same procedures that we finalized in the CY 2013 PFS final rule with comment period (for a description of those procedures, we refer readers to 77 FR 69309 through 69310). Rather than querying Medicare's PECOS data base as of October 15 or another date certain, however, we proposed to perform the query within 10 days of the close of the PQRS group self-nomination/registration process during the relevant performance period year. We proposed to revise the regulations at § 414.1210(c) to reflect that identification of the groups of physicians subject to the value-based payment modifier is based on a query of PECOS at the close of the PQRS registration period and that groups of physicians are removed from this list if, based on a claims analysis, the group of physicians did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. We solicited comment on this proposal.

We did not receive any comments on this proposal; therefore, we are finalizing this proposal without modification.

b. Approach To Setting the Value-Based Payment Modifier Adjustment Based on PQRS Participation

In the CY 2013 PFS final rule with comment period (77 FR 69311), we adopted a policy to categorize groups of physicians subject to the value-based payment modifier in CY 2015 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2015 value-based payment modifier into two categories. Category 1 includes groups that either (a) self-nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group for CY 2013. Groups of physicians in Category 1 may elect to have their value-based payment modifier for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. The value-based payment modifier for groups of physicians in Category 1 that do not elect quality tiering is 0.0 percent, meaning that physicians in these groups will not receive a payment adjustment under the value-based payment modifier for CY 2015. Category 2 includes groups of physicians that do not fall within Category 1. For those groups of physicians in Category 2, the value-based payment modifier for CY 2015 is −1.0 percent.

We proposed to use a similar two-category approach for the CY 2016 value-based payment modifier based on a group of physicians' participation in the PQRS but with different criteria for inclusion in Category 1 (78 FR 43489 through 43490). Category 2 would include those groups of physicians that are subject to the CY 2016 value-based payment modifier and do not fall within Category 1. Our proposal was intended to accommodate the various ways in which physicians can participate in the PQRS in CY 2014—either as a group practice participating in the PQRS GPRO or individually. We established in the CY 2013 PFS final rule with comment period that groups of physicians that wish to participate as a group in the PQRS during CY 2014 must self-nominate and select one of three PQRS GPRO reporting mechanisms: GPRO web interface, qualified registry, or EHR (77 FR 69199–69200 (Table 93)). We also established the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2016 (77 FR 69200–69202), and we proposed to modify these criteria as described in Table 27 of the CY 2014 PFS proposed rule (78 FR 43370). In order to maintain alignment with the PQRS, for purposes of the CY 2016 value-based payment modifier, we proposed that Category 1 would include those groups of physicians that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHRs, or qualified registry reporting mechanisms) for the CY 2016 PQRS payment adjustment.

We explained in the CY 2014 PFS proposed rule (78 FR 43489–43490) that not all groups of physicians may want to participate in PQRS as a group under the GPRO in CY 2014. These groups of physicians may prefer to have all of their eligible professionals continue to report PQRS measures as individuals so that physicians and other eligible professionals in the group are able to report data on quality measures that reflect their own clinical practice. In addition, eligible professionals in these groups of physicians may wish to use different reporting mechanisms to report data for PQRS, such as the claims-based reporting mechanism, EHRs, qualified registries, or the proposed qualified clinical data registry reporting mechanism. Therefore, for the CY 2016 value-based payment modifier, we proposed to include in Category 1 groups of physicians that do not self-nominate to participate in the PQRS as a group practice in CY 2014 and that have at least 70 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. Our intention with this proposal was to align the criteria for inclusion in Category 1 with the criteria that are established for the CY 2016 PQRS payment adjustment.

We also proposed to revise the regulation text at § 414.1225, which was previously specific to the CY 2013 performance period and only referred to quality measures reported by groups of physicians rather than individual eligible professionals within a group. We solicited comment on these proposals. The following is summary of the comments we received regarding these proposals.

Comment: The vast majority of commenters supported our proposal to continue to align the value-based payment modifier with the PQRS reporting mechanisms and to place groups of physicians into two categories for purposes of the value-based payment modifier based upon PQRS participation. Several commenters suggested that such alignment was essential to reduce physician burden. Other commenters highlighted the importance of physicians continuing to have the option to select the clinical quality measures via PQRS (and the appropriate reporting mechanism) that will be used for the calculation of the value-based payment modifier.

Response: We appreciate commenters' support for our proposals. One of the principles governing our implementation of the value-based payment modifier is to align program requirements to the extent possible. Thus, we expect to continue to align the value-based payment modifier with the PQRS program requirements and reporting mechanisms to ensure physicians and groups of physicians report data on quality measures that reflect their practice. We appreciate

commenters' support for our continuation of the two category approach that we proposed for the CY 2016 value-based payment modifier.

Comment: Many commenters supported our proposal to include in Category 1 groups of physicians that do not participate in the PQRS as a group practice in CY 2014 but who have at least 70 percent of the group's EPs meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 payment adjustment. Commenters suggested this proposal is essential for those small group practices that do not participate in the PQRS GPRO and whose individual EPs have reported via the claims reporting mechanism for the past several years. Several commenters, however, suggested that we lower the proposed 70 percent threshold to 50 percent so that more groups can fall into Category 1 through reporting at the individual level. Several commenters supported a lower threshold because of (a) the increased reporting thresholds to avoid the 2016 PQRS payment adjustment, (b) the minimal participation in the PQRS GPRO, which would make this option more attractive, (c) lack of measures for certain sub-specialists that practice in smaller groups, and (d) the transition to ICD–10. One commenter suggested that we utilize a tiered approach by setting the threshold at 25 percent in the first year, 50 percent in the second year, and 75 percent in the third year (and thereafter) in order to allow more groups to be successful in reporting under this option.

Response: We appreciate commenters' support for our proposal to provide a way to combine individually reported PQRS measures into a group score for purposes of the CY 2016 value-based payment modifier. We believe that the value-based payment modifier should recognize the diversity of physician practices and the various measures used to assess quality of care furnished by these practices.

We are persuaded, however, by commenters' suggestion to lower the 70 percent threshold to 50 percent for many of the reasons the commenters stated. We expect to propose in future rulemaking to raise the 50 percent threshold in order to provide a more comprehensive assessment of the quality of care furnished by a group of physicians across a richer set of quality dimensions.

By setting the threshold to 50 percent, we estimate that 76 percent of groups of physicians with between 10 and 19 EPs (based on 2011 PQRS participation) would meet the 50 percent threshold and 45 percent of groups with 100 or more EPs would meet the 50 percent threshold.

Accordingly, we are finalizing our proposal to align the criteria for inclusion in Category 1 with the criteria for the CY 2016 PQRS payment adjustment as referenced above in PQRS Tables 48 and 50, which show the criteria to avoid the CY 2016 PQRS payment adjustment for group practices reporting through the GPRO and individual EPs. For the CY 2016 value-based payment modifier, Category 1 will include those groups of physicians that meet the criteria for satisfactory reporting of data on PQRS quality measures through the GPRO for the CY 2016 PQRS payment adjustment. Category 1 will also include those groups of physicians that do not register to participate in the PQRS as a group practice in CY 2014 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. For a group of physicians that is subject to the CY 2016 value-based payment modifier to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of the 50 percent option) must be met during the CY 2014 performance period for the PQRS CY 2016 payment adjustment. Category 2 will include those groups of physicians that are subject to the CY 2016 value-based payment modifier and do not fall within Category 1. We also are finalizing our proposed revisions to the regulation text at § 414.1225, which was previously specific to the CY 2013 performance period and only referred to quality measures reported by groups of physicians rather than individual eligible professionals within a group.

We proposed to more fully phase-in the quality-tiering methodology for calculating the value-based payment modifier for CY 2016 based on the number of eligible professionals in the group. We proposed that groups in Category 1 would no longer have the option to elect quality tiering for the CY 2016 value-based payment modifier (as was the case for the CY 2015 value-based payment modifier) and instead would be subject to mandatory quality tiering. We proposed to apply the quality-tiering methodology to all groups in Category 1 for the value-based payment modifier for CY 2016, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, we proposed that groups of physicians in Category 1 with between 10 and 99 eligible professionals would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 value-based payment modifier. We stated our belief that this proposed approach would reward groups of physicians that provide high-quality/low-cost care, reduce program complexity, and more fully engage groups of physicians in our plans to implement the value-based payment modifier. Accordingly, we proposed to revise the regulations at § 414.1270 to reflect the proposal to make the quality-tiering methodology mandatory, with the exception noted above, for all groups of physicians subject to the value-based payment modifier in CY 2016 that fall within Category 1. We solicited comment on this proposal.

Comment: Many commenters opposed this proposal for the following reasons: (1) the proposed new PQRS quality reporting mechanisms and requirements for 2014 make it difficult for groups (as identified by the Taxpayer Identification Number (TIN)) to estimate their quality score; (2) the lack of a PQRS aggregate reporting mechanism makes it difficult for medical groups that use multiple TINs to bill Medicare to report on all of its TINs using one reporting mechanism; (3) groups of 100 or more do not yet understand how their cost composites would change given our proposals to add a new cost measure (MSPB) and to change our peer group methodology; (4) groups of 100 or more have not yet seen their 2012 Quality and Resource Use Report, (available September 16, 2013), and which contains how they would fare under the quality-tiering methodology; and (5) not enough time to understand the impact of the new beneficiary attribution method used in the reports and then to use the patient level data in the 2012 QRURs to improve performance before the next performance period (CY 2014).

Some commenters supported the proposal and suggested that the only way to truly drive quality improvements

in the health care delivery system was to measure performance on quality measures and to attach payment consequences to that performance. Several commenters urged us to move away from the ''pay for reporting'' approach that we had adopted for the value-based payment modifier for CY 2015.

Response: We are not persuaded by commenters' concerns with our proposal to require mandatory quality tiering for calculating the value-based payment modifier for CY 2016 and exempt groups of physicians with between 10 and 99 EPs from any downward adjustments derived under the quality-tiering methodology. Based on an analysis of the CY 2012 QRURs that we made available to groups of 25 or more eligible professionals on September 16, 2013, over 80 percent of 3,876 groups for which we could compute both a quality and cost composite score were classified as average quality and average cost, meaning no payment adjustment under the quality-tiering methodology. Slightly over 8 percent of groups of 25 or more EPs would be classified in tiers that would earn an upward adjustment (11 percent of such groups would earn an additional bonus for treating high-risk beneficiaries) and slightly less than 11 percent of groups of 25 or more EPs would be classified in tiers that would involve a downward payment adjustment. Moreover, for the 1,236 groups of 100 or more eligible professionals based on 2012 data, 68 groups would earn an upward adjustments (with 10 groups earning the additional bonus for treating high-risk beneficiaries) and 88 groups would receive a downward adjustment using the quality-tiering methodology. These results suggest that our quality-tiering methodology identifies a small number of groups of physicians that are outliers—both high and low performers—in terms of whose payments would be affected by the value-based payment modifier, thus limiting any widespread unintended consequences. In addition, we are adopting policies in this final rule to address certain aspects of our previously established methodologies so that beginning in CY 2016 we better assess the group of physicians' quality of care furnished or the cost of that care. These policies include our refinement of the cost composite peer group methodology and the use of PQRS quality data reported by individual EPs. As explained above in section III.K.4.a, we will continue to monitor the value-based payment modifier program and continue to examine the characteristics of those groups of physicians that could be subject to an upward or downward payment adjustment under our quality-tiering methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

To address commenters' specific concerns about mandatory quality tiering, we believe groups of physicians will report data for quality measures under PQRS on which they expect their performance would be high, regardless of whether it is a new reporting mechanism or the reporting requirements may have changed for CY 2014. Thus, we disagree with the assertion that groups of physicians must receive a QRUR from CMS before they can understand their performance on quality measures on which they choose to report data. Notwithstanding this observation, the PQRS since 2007 has provided feedback reports to physicians on their performance on reported quality measures so that physicians can see how they compare against others who report the same measures. We also disagree with commenters who suggest that we do not have a quality reporting system that allows large health systems that use multiple TINs to bill Medicare to use one method. The Medicare Shared Savings Program provides a way for large systems (a) to use one reporting mechanism that aggregates their multiple TINs into one organization, (b) to fulfill their PQRS obligations, and (c) to earn savings for furnishing high quality/low cost care.

Further, on September 16, 2013, we made available to all groups of 25 or more EPs an annual QRUR based on 2012 data to help groups estimate their quality and cost composites, thus groups of 100 ore more eligible professionals have had access to their reports. Moreover, these reports provide beneficiary specific information, including hospitalization information for attributed beneficiaries that enables groups of physicians to examine which beneficiaries are driving performance on quality outcome measures and the cost measures. We intend to provide QRURs to all groups of physicians and solo practitioners during the summer of 2014 (based on 2013 performance) that include their performance on the MSPB measure and the new peer group methodologies. Thus, we believe all groups of 100 or more have, or will soon have, the data necessary to begin to improve performance. Although we are sensitive to providing groups of physicians with adequate lead time to understand the impact of the beneficiary attribution method used for the value-baed payment modifier, we believe our policy of holding groups of between 10 and 99 EPs harmless from any downward payment adjustment would likely mitigate unintended consequences that could occur. In addition, the attributed beneficiaries in the 2012 QRURs had, on average, at least three primary care services furnished by physicians in the group. We believe such information could help groups of physicians estimate which beneficiaries in their patient population may be attributed to them prior to receiving a QRUR that includes data from the relevant performance period.

Comment: Many commenters appreciated the policy to hold harmless groups of physicians with between 10 and 99 EPs from any negative payment adjustments and supported our proposal. A few commenters suggested that applying the value-based payment modifier negative payment adjustment only to groups of 100 or more EPs is an unjust payment methodology because CMS is not holding smaller group practices to the same quality standards as larger group practices. Several commenters also suggested that by eliminating the negative payment adjustment for small group practices, CMS is decreasing the maximum incentive amount a high quality/low cost large group practice could receive under the quality-tiering approach.

Response: We appreciate commenters' support for our proposal. Our focus as we implement the value-based payment modifier is to increase quality measurement, because without measurement we do not believe that we can have consistent and sustained quality of care improvements for Medicare FFS beneficiaries. Large groups practices are more likely to have the ability and means to track and monitor quality of care and resource use whereas many smaller groups are now just developing these capabilities. Thus, we believe it is appropriate to hold groups of physicians with between 10 and 99 EPs harmless from any downward adjustments, which is similar to the policy we are applying to groups of 100 or more EPs during the first year the value-based payment modifier applies to them (2015). We recognize that until the value-based payment modifier is fully implemented, with both upside and downside adjustment applied to all groups of physicians and solo practitioners, we will have disparate impacts and the pool of money available for upward adjustments will be reduced. We believe, however, this policy is

consistent with our overall approach to gradually phase in the value-based payment modifier and reinforces our goal to increase quality reporting while not increasing reporting burdens on physicians.

For these reasons, we are finalizing our proposal that groups of physicians in Category 1 will not have the option to elect quality tiering for the CY 2016 value-based payment modifier and instead will be subject to mandatory quality tiering. We also are finalizing our proposal that groups of physicians in Category 1 with between 10 and 99 eligible professionals will be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 value-based payment modifier. We are also finalizing the revision to the regulations at § 414.1270 to clarify that for the CY 2015 payment adjustment period a group may be determined under the quality-tiering methodology to have low performance based on low quality and high costs, low quality and average costs, or average quality and high costs.

c. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the value-based payment modifier; however, section 1848(p)(4)(C) of the Act requires the value-based payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians based on high performance and decrease for others based on low performance, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value-based payment modifier.

In the CY 2013 PFS final rule with comment period, we adopted a modest payment reduction of 1.0 percent for groups of physicians in Category 1 that elected quality tiering and were classified as low quality/high cost and for groups of physicians in Category 2 (77 FR 69323–24).

As discussed in the CY 2014 proposed rule (78 FR 43500 through 43502), we conducted statistical reliability analysis on the PQRS quality measures and the cost measures contained in the 2010 and 2011 group and individual QRURs. These QRURs contained the quality measures that were reported under the PQRS and five per capita cost measures that we will use for the value-based payment modifier. The quality and cost measures in the group QRURs were very statistically reliable. Moreover, the average reliability was high for 98 percent of the individually reported PQRS measures and for all of the cost measures (with a case size of at least 20) included in the individual QRURs. Thus, we noted our belief that we can increase the amount of payment at risk because we can reliably apply a value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals and to smaller groups and to solo practitioners in future years. Therefore, we proposed to increase the downward adjustment under the value-based payment modifier from 1.0 percent in CY 2015 to 2.0 percent for CY 2016. That is, for CY 2016, a –2.0 percent value-based payment modifier would apply to groups of physicians subject to the value-based payment modifier that fall in Category 2. In addition, we proposed to increase the maximum downward adjustment under the quality-tiering methodology to –2.0 percent for groups of physicians classified as low quality/high cost and to set the adjustment to –1.0 percent for groups classified as either low quality/average cost or average quality/high cost. We proposed to revise § 414.1270 and § 414.1275(c) and (d) to reflect the proposed increase to a 2.0 percent adjustment under the value-based payment modifier for the CY 2016 payment adjustment period. We also made a technical correction to § 414.1275(c) to clarify the PQRS GPRO reporting mechanisms available in CY 2013. Table 85 shows the proposed quality-tiering payment adjustment amounts for CY 2016 (based on CY 2014 performance).

TABLE 85—2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS

CY 2016			
Cost/Quality	Low quality	Average quality	High quality
Low cost	+0.0%	+1.0x*	+2.0x*
Average cost	–1.0%	+0.0%	+1.0x*
High cost	–2.0%	–1.0%	+0.0%

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

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period, the upward payment adjustment factor (''x'') would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We noted that any funds derived from the application of the downward adjustments to groups of physicians with 100 or more eligible professionals and the downward 2.0 percent adjustment applied to those groups of physicians subject to the value-based payment modifier that fall in Category 2, would be available to all groups of physicians eligible for value-based payment modifier upward payment adjustments. The quality-tiering methodology would continue to provide an additional upward payment adjustment of +1.0x to groups of physicians that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). We solicited comments on our proposal to increase the downward value-based payment modifier to 2.0 percent for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are classified as low quality/high cost groups for the CY 2016 payment adjustment period.

The following is summary of the comments we received regarding this proposal.

Comment: A number of commenters supported our proposal to increase the amount of payment at risk under the value-based payment modifier in CY 2016. Some commenters stated that the payment adjustment must be of significant weight in order to drive physician behavior toward achieving high quality and low cost care. A few commenters suggested that the value-based payment modifier should represent a larger percentage of

physician payments under the PFS and stated that the amount of the payment differential should be closer to 10.0 percent, increased incrementally from 2.0 percent and subject to annual review.

Many commenters, however, were opposed to our proposed policy. Several commenters suggested that CMS should not increase the amount of payment at risk under the value-based payment modifier in CY 2016 and recommended keeping the amounts at the CY 2015 levels. A few commenters urged CMS to delay increasing the maximum downward adjustment under the program until at least CY 2017 to allow CMS to gain experience with applying the value-based payment modifier to a broader variety of groups, and to allow physician groups to increase their understanding of their performance under quality-tiering. Some commenters suggested keeping the downward adjustments for groups subject to the value-based payment modifier at −1.0 percent during the first year and then increasing it to −2.0 percent during the second year. Some commenters indicated that groups that report data and choose to elect quality-tiering should not be at the same risk as groups that did not report at all. Some commenters also indicated that a large number of physicians could see both a two percent PQRS and a two percent value-based payment modifier adjustment in 2016, and when added to a potential two percent sequester reduction, and possibly another two percent EHR adjustment, this could push some older physicians to retire or close their practices to Medicare patients. One commenter indicated that it does not agree that the size of PQRS and value-based payment modifier adjustments is the driving factor in physicians' decisions on whether to participate in these incentive programs.

Response: We agree with the commenters who stated that the amount of payment at risk should be higher than the 1.0 percent amount of payment at risk in 2015 in order to incentivize physicians to provide high quality and low cost care. Our experience under PQRS has shown us that a 1.0 or 2.0 percent incentive payment was insufficient to obtain widespread participation in the PQRS, thus, we believe that we need to increase the amount of payment at risk for the CY 2016 value-based payment modifier in order to incentivize physicians and groups of physicians to report PQRS data, which will be used to calculate the value-based payment modifier. Therefore, we are finalizing our proposal to increase the maximum downward adjustment for the CY 2016 value-based payment modifier to 2.0 percent for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are in Category 1 and are classified as low quality/high cost groups. We also believe that our final policy, as described above in section III.K.4.b, to calculate for a group of physicians the performance on PQRS quality measures reported by individual eligible professionals in the group will enable more groups to fall under Category 1 and avoid Category 2's automatic −2.0 percent payment adjustment. Even though several commenters suggested that we increase incrementally the amount of payment at risk to 10 percent, we believe that it is premature in this final rule with comment period to lay out the roadmap for future years as suggested by these commenters.

After consideration of the comments received and for the reasons stated previously, we are finalizing our proposed policies as described above.

d. Performance Period

In the CY 2013 PFS final rule with comment period (77 FR 69314), we adopted a policy that performance on quality and cost measures in CY 2014 will be used to calculate the value-based payment modifier that is applied to items and services for which payment is made under the PFS during CY 2016. We received comments in response to the CY 2013 PFS proposed rule requesting that we close the gap between the end of the performance period (for example, December 31, 2014) and the beginning of the payment adjustment period (for example, January 1, 2016), in order to strengthen the connection between the performance of physicians and groups of physicians and the financial incentives for quality improvement.[3] We understand that many private sector plans start to provide payment adjustment within 7 months of close of the performance period.[4]

Since the payment adjustment periods for the value-based payment modifier are tied to the PFS, which is updated on an annual calendar year basis, options to close the 1-year gap between the close of the performance period and the start of the payment adjustment period are limited and primarily are centered around altering the start and end dates of the performance period. As discussed previously in section III.H. of this final rule with comment period, one option could be to adjust the performance period for quality data reported through the PQRS. In addition, we could calculate the total per capita cost measures on an April 1 through March 31 basis, thus closing the gap by 3 months.

However, a byproduct of altering the performance periods is that the deadline for submitting quality information would have to occur promptly at the end of the performance period. In addition, the review period during which groups of physicians will be able to review the calculation of the value-based payment modifier would be shortened to allow the necessary system changes to implement the adjustment by the January 1 deadline for implementation of the annual PFS. We solicited comment on the potential merits of altering our current performance periods.

We proposed to use CY 2015 as the performance period for the value-based payment modifier adjustments that will apply during CY 2017. We believe it is important to propose the performance period for the payment adjustments that will apply in CY 2017, because section 1848(p)(4)(B)(iii) of the Act requires all physicians and groups of physicians to be subject to the value-based payment modifier beginning not later than January 1, 2017. Accordingly, we proposed to add a new paragraph (c) to § 414.1215 to indicate that the performance period is CY 2015 for value-based payment modifier adjustments made in the CY 2017 payment adjustment period. We solicited comment on this proposal.

The following is a summary of the comments we received.

Comment: Many commenters expressed the opinion that shortening the gap between the performance year and the adjustment year for the value-based payment modifier by 3 months does not represent a significant improvement. Commenters indicated that CMS should continue to seek ways to reduce the current 1-year gap between the close of the performance period and the beginning of the payment adjustment period. A number of commenters recommended that CMS adjust the performance period for quality data reported through PQRS and calculate the total per capita cost measures on an April 1 through March 31 basis, thus closing the gap by 3 months. Other commenters indicated

[3] See, e.g., Comment of the American College of Surgeons comment on the CY 2013 PFS proposed rule (Aug. 31, 2012).

[4] US GAO, Medicare Physician Payment: Private-Sector Initiatives Can Help Inform CMS Quality and Efficiency Incentive Efforts, GAO–13–160 (Dec. 2012), available at *http://www.gao.gov/assets/660/651102.pdf.*

that the increasing use of the new PQRS qualified clinical data registry reporting option can provide a window to reduce this gap considerably, a rolling 12-month cycle reported on a quarterly basis may be most effective for measurements with small sample populations, and a longer period of time may be required to show any improvement.

Response: A majority of the commenters did not support the option to adjust the performance period for quality data reported through PQRS and calculate the total per capita cost measures on an April 1 through March 31 basis and claimed that closing the gap by 3 months would not be a significant improvement. Also, there was not sufficient support among commenters for reporting PQRS data on a quarterly basis because it would be operationally difficult and burdensome on physicians. Therefore, we are finalizing a policy to use CY 2015 as the performance period for the value-based payment modifier adjustments that will apply during CY 2017. In the meantime, we will continue to consider options to close the gap between the performance period and the payment adjustment period and will continue to provide timely feedback to physician groups through the QRURs. One potential mechanism to close the gap would be to require quarterly reporting by eligible professionals or to truncate the time allowed for reporting after the performance period closes; however, we have not received comments from physicians and other clinicians supporting these approaches. Moreover, we believe it is critical to calculate cost measures using a full 90 day claims runout so that measures accurately assess the cost of care. We encourage stakeholders to share their thoughts and ideas on options to close the gap without imposing an undue administrative burden and while still allowing for meaningful quality and costs measurement. In the meantime, we expect that groups of physicians will become even more proficient at the use of EHR technology and establish real-time feedback on quality measures so that they have relevant performance information that they can act on at the point of care.

e. Quality Measures

In the CY 2013 PFS final rule with comment period (77 FR 69315), we aligned our policies for the value-based payment modifier for CY 2015 with the PQRS reporting mechanisms available to groups of physicians in CY 2013, such that data that a group of physicians submitted for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2013 would be used for calculating the quality composite under the quality-tiering approach for the value-based payment modifier for CY 2015. Moreover, all of the quality measures for which groups of physicians are eligible to report under the PQRS in CY 2013 are used to calculate the group of physicians' value-based payment modifier for CY 2015, to the extent the group of physicians submits data on such measures. We also established a policy to include three additional quality measures (outcome measures) for all groups of physicians subject to the value-based payment modifier: (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia, and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

PQRS Reporting Mechanisms: We noted in the proposed rule that we believe it is important to continue to align the value-based payment modifier for CY 2016 with the requirements of the PQRS, because quality reporting is a necessary component of quality improvement. We also seek not to place an undue burden on physicians to report such data. Accordingly, for purposes of the value-based payment modifier for CY 2016, we proposed to include all of the PQRS GPRO reporting mechanisms available to group practices for the PQRS reporting periods in CY 2014 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2014. In addition, we proposed that groups of physicians with 25 or more eligible professionals would be able to elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2014 in their value-based payment modifier for CY 2016. These reporting mechanisms are described in Tables 24 through 27 of the CY 2014 PFS proposed rule (78 FR 43367–43370). We also proposed to update our regulations at § 414.1220 to reflect this proposal. We noted in our proposal that the criteria for satisfactory reporting of data on PQRS quality measures for individual eligible professionals via qualified registries for the CY 2014 PQRS incentive and CY 2016 PQRS payment adjustment permits the use of a 6-month reporting period. We stated that we believed that data submitted via qualified registries for this 6-month reporting period would be sufficiently reliable on which to base a group of physicians' quality composite score under the value-based payment modifier because in order for us to use the data to calculate the score, we would require data for each quality measure on at least 20 beneficiaries, which is the reliability standard for the value-based payment modifier (77 FR 69322–69323). Given this level of reliability, we believe a 6-month reporting period would be sufficient for the purpose of evaluating the quality of care furnished by a group of physicians subject to the value-based payment modifier. We solicited comment on this proposal. The following is a summary of the comments we received on this proposal.

Comment: The majority of commenters supported our proposal to permit groups practices and individual EPs to use all of the PQRS reporting mechanisms available to them in CY 2014 for the value-based payment modifier, including the use of the PQRS CAHPS survey. Commenters indicated that there should be a wide range of reporting options available in order to increase participation in the PQRS. Others commenters urged us to the retain the PQRS Administrative Claims reporting option that we have in place for CY 2013 and to include in Category 1 those groups of physicians that elect the Administrative Claims option.

Response: We appreciate the comments received in support of our proposal. As discussed previously, one of the principles governing our implementation of the value-based payment modifier is that physicians should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting physicians' choice over their practice configurations. We believe that the various PQRS reporting mechanisms—which include both individual and group reporting mechanisms allow physicians to choose how best to report quality information given their practice configuration. In response to the commenters' suggestion that we continue to use the PQRS Administrative Claims reporting option for the value-based payment modifier, we believe this option does not match our long-term goals to encourage reporting by physicians and groups of physicians of quality measures that best match their practices. In addition, our analysis of the CY 2012 QRURs shows that average reliability is substantially higher for the PQRS measures reported by physicians and groups of physicians

than the reliability of many of the 14 Administrative Claims measures.

Accordingly, we are finalizing our proposal to include for the CY 2016 value-based payment modifier all of the PQRS GPRO reporting mechanisms available to group practices for the PQRS reporting periods in CY 2014 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2014. In addition, we are finalizing our proposal that groups of physicians with 25 or more eligible professionals would be able to elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2014 in their value-based payment modifier for CY 2016. We are finalizing the corresponding changes to § 414.1220 as proposed.

PQRS Quality Measures: We also proposed to use all of the quality measures that are available to be reported under these various PQRS reporting mechanisms, including quality measures reported through qualified clinical data registries, to calculate a group of physicians' value-based payment modifier in CY 2016 to the extent that a group of physicians submits data on these measures. We noted that the three outcome measures that we finalized in the CY 2013 PFS final rule with comment period and in § 414.1230—the two composites of rates of potentially preventable hospital admissions and the all-cause hospital readmission measure—would continue to be included in the quality measures used for the value-based payment modifier in CY 2016.

For those groups of physicians subject to the value-based payment modifier in CY 2016 whose eligible professionals participate in the PQRS as individuals rather than as a group practice under the GRPO (that is, groups of physicians that are assessed under the finalized 50 percent threshold), we proposed to calculate the group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. We noted that if all of the eligible professionals in a group of physicians subject to the CY 2016 value-based payment modifier satisfactorily participate in a PQRS qualified clinical data registry in CY 2014 and we are unable to receive quality performance data for those eligible professionals, for purposes of the value-based payment modifier, we proposed to classify the group's quality composite score as ''average'' under the quality-tiering methodology, because we would not have data to reliably indicate whether the group should be classified as high or low quality under the quality-tiering methodology. We also proposed to add a new subsection to our regulations at § 414.1270 to reflect our proposals about how to assess quality performance for groups assessed under the proposed 70 percent threshold ((which is being finalized as 50 percent, as discussed above). We solicited comment on these proposals.

The following is a summary of the comments we received regarding these proposals.

Comment: Most commenters supported use of all PQRS measures available to groups of physicians and individual physicians and eligible professionals for the CY 2014 PQRS reporting periods. The commenters appreciated ''CMS' flexibility in allowing performance on all PQRS measures to be included in the value-based payment modifier.'' Several commenters expressed concern over the lack of measures in the PQRS measure set that are appropriate for certain specialties and urged that these specialties not be penalized under the value-based payment modifier solely based on the limited availability of quality measures for those specialties. One commenter, however, suggested that rather than straining Medicare's limited resources to implement dozens of process measures and shortening reporting times, we should use a small number of outcome measures (calculated at the population level within a specified geographic area) that are important to taxpayers and beneficiaries for the value-based payment modifier.

We did not receive comments on our proposal to calculate a group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. Despite the lack of comments on how we should calculate a group score when EPs in the group report PQRS quality measures as individuals, commenters cited our proposal to address the potential scenario of not receiving data from qualified clinical data registries as a ''reasonable way'' to tier groups whose EPs report using a PQRS qualified clinical data registry in CY 2014.

Response: We appreciate commenters' support for our proposals. We believe that the PQRS measure set is robust and, as described above, we have included new measures to address measure gaps (section III.H.9. above). In addition, we have collaborated with the specialty societies in order to increase the number of measures available specifically for specialists. We appreciate the suggestion to use a small number of outcome measures calculated at the population level, and we will continue to examine ways to add to the three outcome measures that we currently utilize for the value-based payment modifier as we continue our implementation of the value-based payment modifier.

We also note that we expect to receive data in a timely manner for EPs who report using qualified clinical data registries (see discussion above section III.H). For that reason, it is not absolutely necessary that we finalize our proposal to classify as ''average'' under the quality-tiering methodology a group of physicians subject to the CY 2016 value-based payment modifier that falls under Category 1 and whose individual EPs satisfactorily participate in a PQRS qualified clinical data registry in CY 2014. Nonetheless, out of an abundance of caution, we are finalizing the proposal as a precaution to address the scenario where in fact we would be unable to receive data in a timely manner for a group's EPs.

Accordingly, we are finalizing our proposal to use all of the quality measures that are available to be reported under the various PQRS reporting mechanisms to calculate a group of physicians' CY 2016 value-based payment modifier to the extent that the group (or individual EPs in the group, in the case of the 50 percent threshold option) submits data on those measures. We also are finalizing our proposal for those groups of physicians availing themselves of the ''50 percent threshold option'' discussed above to calculate the group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. In addition, for those groups assessed under the ''50 percent threshold option,'' we are finalizing our proposal to classify a group's quality composite score as ''average'' under the quality-tiering methodology, if all of the eligible professionals in the group satisfactorily participate in a PQRS qualified clinical data registry in CY 2014 and we are unable to receive quality performance data for those eligible professionals. We clarify that if some EPs in the group report data using a qualified clinical data registry and we are unable to obtain the data, but other EPs in the group report data using claims, registry, or EHR reporting

mechanism, we would calculate the group's score based on the reported performance data that we obtain through claims, registries, or EHRs. We are finalizing our proposed addition to the regulations at § 414.1270 without modification.

We noted that when the value-based payment modifier applies to all physicians and groups of physicians in CY 2017 based on performance during CY 2015, we anticipate continuing our policy to align with the PQRS group reporting for all groups of physicians of two or more eligible professionals, and we anticipate permitting physicians who are solo practitioners to use any of the PQRS reporting mechanisms available to them under the PQRS for reporting periods in CY 2015 for purposes of the value-based payment modifier in CY 2017. Although we did not propose to adopt this policy, we solicited comment on this approach to align certain aspects of the CY 2017 value-based payment modifier with the quality measures and reporting mechanisms used in the PQRS.

Comment: Commenters supported the approach to align the CY 2017 value-based payment modifier with the PQRS quality measures and the available PQRS reporting mechanisms. The commenters recognize that with the PQRS they have a choice of measures that serve as the basis for assessment. They also believe that alignment between the PQRS and the value-based payment modifier helps to minimize administrative burden to physician practices. Commenters encouraged ''CMS to continue in future rulemaking cycles to allow physicians the flexibility to choose measures that are applicable to their scope of practice.''

Response: We appreciate the commenters' support for our overall approach to the CY 2017 value-based payment modifier. We anticipate making proposals in future rulemaking to apply the value-based payment modifier to all physicians and groups of physicians in 2017.

f. Inclusion of the Medicare Spending per Beneficiary Measure in the Value-Based Payment Modifier Cost Composite

In the CY 2014 PFS proposed rule, we summarized the five cost measures that we previously finalized for the value-based payment modifier cost composite and restated our previously expressed belief that the value-based payment modifier should incorporate additional measures that are consistent with the National Quality Strategy and other CMS quality initiatives. As a step toward that goal, beginning with the CY 2016 value-based payment modifier, we proposed to expand the cost composite to include an additional measure, the Medicare Spending per Beneficiary (MSPB) measure (with one modification as discussed in the CY 2014 PFS proposed rule) (78 FR 43493 through 94). We proposed that the MSPB measure would be added to the total per capita costs for all attributed beneficiaries domain of the value-based payment modifier. We proposed that the MSPB measure would be equally weighted with the other cost measure in that domain—the total per capita cost measure. We stated that the rationale for our proposal to include the MSPB measure in the total per capita costs for all attributed beneficiaries domain, rather than the total per capita costs for all attributed beneficiaries with specific conditions domain, was that the MSPB measure is similar to the total per capita costs measure.

In addition, we stated our intent to propose, in future rulemaking, to replace the four measures in the total per capita costs for all attributed beneficiaries with specific conditions domain with cost measures derived from the CMS Episode Grouper and other episode-based costs. We solicited comments on these potential changes to the condition-specific cost measures as well as on the other elements of the cost composite in preparation for the CY 2015 performance period affecting payment adjustment year CY 2017.

In the proposed rule, we provided background on the MSPB measure, which we have already finalized for inclusion in the Hospital Inpatient Quality Reporting (IQR) and Value-Based Purchasing (VBP) Programs. We stated that, when viewed in light of other quality measures, as a part of the value-based payment modifier measure set, we believe that inclusion of the MSPB measure would enable us to align incentives and similarly recognize physician groups involved in the provision of high-quality care at a lower cost to Medicare.

Construction of the MSPB measure. In the CY 2014 PFS proposed rule, we summarized the construction of the MSPB measure used for the Hospital IQR and VBP Programs (78 FR 43494). We stated that the measure includes all Medicare Part A and Part B payments during an MSPB episode spanning from 3 days prior to an index hospital admission through 30 days post discharge with certain exclusions. Costs for each episode are risk adjusted and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. The payment standardization is the same methodology used for the existing total per capita cost measures included in the value-based payment modifier. We explained that, under the Hospital IQR and VBP Programs, the payment-standardized costs for all index admissions are summed and divided by the sum of the expected costs from the risk adjustment model. This ratio is then multiplied by the national average MSPB episode cost to give the hospital's MSPB amount. We then divide an individual hospital's MSPB amount by the national median MSPB amount to calculate a ratio, which we publicly report on Hospital Compare and use to generate a measure score for the Efficiency domain under the Hospital VBP Program. We referred readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for a detailed description of the MSPB measure used in the Hospital IQR and VBP Programs and noted that a detailed specification document (entitled ''MSPB Measure Information Form'') and the payment standardization methodology (entitled ''CMS Price Standardization'') can be found in the ''Measure Methodology'' section at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*.

We proposed a slightly revised calculation for inclusion of the MSPB measure in the value-based payment modifier. We proposed not to convert the MSPB amount to a ratio as is done to compute a hospital's MSPB measure under the Hospital IQR and VBP Programs, but rather to use the MSPB amount as the measure's performance rate. We solicited comment on our proposals to include the MSPB measure (as modified per the discussion above) in the value-based payment modifier cost composite and to add the measure to the total per capita costs for all attributed beneficiaries domain. We also proposed to revise the regulations at § 414.1235 to include the Medicare Spending per Beneficiary measure in the set of cost measures for the value-based payment modifier and § 414.1260(b)(1)(i) to include the Medicare Spending per Beneficiary measure in the total per capita costs for all attributed beneficiaries domain. We received many comments on our proposal to include the MSPB measure as a part of the cost composite for the Physician Value-Based Payment Modifier beginning with the CY 2014 performance period and CY 2016 payment adjustment year.

Comment: Many commenters opposed our proposal to include the MSPB measure in the cost composite. While

several of these acknowledged the importance of promoting efficiency for physicians and incentivizing coordination of care and reduction in delivery system fragmentation, they expressed reservations regarding implementation of the measure for the CY 2014 performance year and the CY 2016 value-based payment modifier. The reasons given for the lack of support for this measure's addition to the cost composite included: lack of experience with this measure as it applies to physicians and physician groups, with the suggestion that it first be piloted or included in PQRS or Quality and Resources Use Reports (QRURs) before it is included in the value-based payment modifier; lack of NQF endorsement; perceived lack of physician control over care plan; concerns about actionability, that is, whether the information from the measure can be used by physician groups to improve performance; or perceived lack of measure specification or testing at the physician level. One commenter suggested that the measure first be piloted on populations with clearly inappropriate spending patterns. One commenter questioned the applicability of the measure to physician groups practicing in dedicated cancer centers, and two expressed that measure variation was not reflective of pathology services. One of these commenters suggested that the Hospital VBP Program total performance score for the hospital in which a pathologist practices should be used in the value-based payment modifier, rather than the MSPB measure rate.

Response: We agree with the commenters that coordination of care and reduction of delivery system fragmentation are important goals and inclusion of this measure in the value-based payment modifier is an important step toward incentivizing quality improvements. We also agree that it is important for physician groups to gain experience with the measure. Accordingly, we will begin including information on the MSPB measure (that is, performance rate, beneficiary information) in the QRURs that will be disseminated to all groups in 2014 based on 2013 performance (and going forward), before it is included in the CY 2016 value-based payment modifier that will adjust physician groups' payments based on 2014 performance. We also note that during the first year the measure is included in the value-based payment modifier, groups of physicians with 10–99 eligible professionals in Category 1 will not receive any downward payment adjustments under the quality-tiering methodology. Because we are finalizing our proposal to ''hold harmless'' groups of physicians with 10–99 EPs in Category 1 from any downward payment adjustment in CY 2016, we believe this policy addresses commenters' concerns, because it means that these groups will have at least 2 years' experience with the measure before it could affect payments. We believe that piloting the measure is not necessary, because hospitals already are being assessed with this measure under the Hospital IQR and VBP Programs, and we seek to align incentives among hospitals and physicians as quickly as possible. We thank the same commenter for the suggestion to use the total performance score for the hospital in which a pathologist practices rather than the MSPB measure, and will take this proposal under consideration in future rulemaking. While groups of 100 or more eligible professionals could potentially receive a downward payment adjustment under the CY 2016 value-based payment modifier (based on their CY 2014 performance), those groups also will have received a QRUR of their measure performance in advance of the performance being used in the value-based payment modifier. We also note that all groups of 25 or more eligible professionals were able to obtain a QRUR based on CY 2012 performance that provided detailed information about the beneficiaries attributed to their groups. These 2012 reports provided details about the beneficiaries' hospitalizations, so that physician groups may begin to work with the hospitals that treat their attributed beneficiaries to improve care coordination, decrease fragmentation, and improve efficiency. We believe that these steps are sufficient to allow physician groups to gain experience with the MSPB measure and do not believe that it would be necessary to first implement the measure on some subset of physician groups that might be expected to have inappropriately high spending. We disagree that the measure is not adequately specified for application to physician groups. As we noted in the proposed rule (78 FR 43494), the measure's detailed specifications are available in the ''Measure Information Form'' located under the ''Measure Methodology'' section on Quality Net (*http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*).

We disagree with commenters' suggestion that physicians have little control over the care provided to beneficiaries who are hospitalized. As noted by some commenters on this proposed rule, as well as on the FY 2013 IPPS proposed rule, there is value in aligning incentives between hospitals and the physicians who practice in them. We acknowledge that physician groups may contribute to the MSPB episode cost to varying degrees. As discussed in more detail below, we are finalizing an attribution methodology that we believe addresses commenters' concerns regarding the degree to which a given physician group contributed to the costs for a given MSPB episode. By attributing episodes included in the MSPB measure only to the physician group that provided the plurality of Part B services during the hospital stay, we believe we are recognizing the group of physicians that is in a strong position to improve coordination, decrease fragmentation, and control Medicare expenditures. In addition, the physician group that provided the plurality of Part B services during the stay is in a strong position to coordinate care with the hospital, addressing commenter concerns about measure actionability discussed above. While we appreciate the value of NQF endorsement, we note that it is not required for inclusion of a measure in the value-based payment modifier. We intend to submit the physician version of the MSPB measure through a future endorsement project; however, at this time, we have proposed a measure that is substantially similar to that currently undergoing the NQF endorsement process, which is a measure used to assess spending for hospitals, rather than physician groups. We believe that inclusion of the MSPB measure in the value-based payment modifier will help to align incentives and promote coordination of care and improved efficiency across provider types, including hospitals and the physician groups who practice in them.

We do not believe it would be appropriate to exclude any physician specialty from inclusion in the measure, as such an exclusion could undermine the effort to incentivize care coordination. We also note that the MSPB measure is built around index admissions at IPPS hospitals, not PPS-exempt cancer hospitals.

Comment: Several commenters expressed their support for inclusion of the MSPB measure in the cost composite. The reasons these commenters provided for their support included: the belief that a robust cost measure set will further transform the Medicare payment system to a system that rewards efficient, effective care and helps address the critical issue of health care; valuing consistency with the use of

this measure in the Hospital VBP Program; and the belief that inclusion of this measure could incentivize team-based care among hospitals and their physicians, including improved discharge planning better discharge instructions and education. One commenter also noted that measurement using the MSPB measure enables providers to develop their own care delivery processes in order to improve performance on the measure. One commenter supported the inclusion of the MSPB measure while suggesting that CMS also continue to explore how cost measures for specific conditions or treatments might be used to further expand the cost composite.

Response: We thank the commenters for their support of our proposal to include the MSPB measure in the cost composite for the value-based payment modifier. We agree that this measure's inclusion will contribute to the continued development of a more robust cost measure set for the value-based payment modifier and that it will incent improved care coordination among physicians and hospitals, improved efficiency, and control of health care costs, and it will help to align incentives across our incentive payment programs. We agree that continuing to expand the cost composite measure set would benefit the value-based payment modifier, and we will consider including specific episode cost measures through future rulemaking.

Comment: We received several comments related to the construction of the MSPB measure itself. One commenter expressed concern with the measure's inability to assess physician groups and their ability to avoid hospitalization for their patients, while several suggested that the risk adjustment methodology should go further to address factors including: socioeconomic status, dual eligibility for Medicare and Medicaid, a frailty factor, functional status, sub-specialty of the physician; place of service; or CPT codes, rather than Major Diagnostic Categories (MDCs). A few commenters expressed concern that a lack of specialty mix could penalize physician practices that focus on home health, skilled nursing facility care, or rehabilitation. A few commenters stated that a measure of provider-level care would be more reliable than one of facility-level or mixed facility- and provider-level care. A few commenters also expressed concern that the measure does not include Part D data. Finally, a few commenters expressed concern that the fact that the MSPB measure does not reflect other aspects of care quality could lead to the unintended consequence of reduced access to or provision of needed care or avoidance of complex patients. One of these commenters suggested that MSPB should therefore not be weighted more heavily than patient experience or outcome measures.

Response: We appreciate the commenters' consideration of the MSPB measure, and we will continue to consider ongoing refinements to it, as we gain experience with the measure. We proposed to use the MSPB amount as the measure rate under the physician value-based payment modifier, rather than converting it to a ratio as we do under the Hospital IQR and VBP Programs. For each cost measure finalized for use in the physician value-based payment modifier, including the MSPB amount, we also are finalizing use of a specialty adjustment that allows for peer group comparisons while factoring in specialty mix (see section III.K.4.g.2. below). The specialty adjustments are made to risk-adjusted dollar amounts, rather than to ratios such as those used under the Hospital IQR and VBP programs. Aside from that proposed difference in expression of the measure rate, we believe that it is important to maintain the measure's construction as closely as possible to that used under the Hospital VBP and IQR Programs, in the interest of alignment across programs and to provide consistent information to both hospitals and their physicians so that they are assessed against the same yardstick. We disagree that inclusion of this measure would incentive physicians to reduce provision of needed care to the beneficiaries they serve and avoid hospitalizations. As we stated in the FY 2013 IPPS/LTCH Final Rule (77 FR 53586), we do not believe that the Medicare Spending per Beneficiary measure itself should assess both cost and quality. We believe that a distinct measure of cost, independent of quality, enables us to identify providers involved in the provision of high quality care at a lower cost to Medicare. Because the MSPB measure would be only one of six measures included in the value-based payment modifier's cost composite, we believe that physicians' consideration for their patients' well-being as well as their performance on the other measures used for the value-based payment modifier would outweigh any potential incentive to reduce needed care to Medicare beneficiaries. We therefore believe that a cost composite weight that is equal to the quality composite weight provides a balance between incentives for physician groups to improve quality and to control cost. We will monitor for changes in utilization patterns. We disagree that the costs of care provided in the facility should be separated from those provided post-discharge. This would be counter to the goal of incentivizing coordination between hospitals and physician group to ensure that Medicare beneficiaries receive effective, efficient care during and after hospitalization. We refer the reader to section III.K.4.g.2., Cost Composite Benchmarking and Peer Groups, for a discussion of the specialty adjustment for the MSPB measure, which addresses the commenter suggestion about specialty adjustment. That adjustment is made outside the construction of the MSPB measure itself and will be performed after the measure is calculated for a group of physicians. We do not believe that payments included in the MSPB measure should be adjusted for differences in site of service, as these differences reflect actual costs to the Medicare program. The payments included in the measure are adjusted according to the CMS Price Standardization methodology located at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=Qnet Public%2FPage%2FQnet Tier4&cid=1228772057350*, and they are standardized to remove differences attributable to geographic payment adjustments and other payment factors. Because many Medicare fee-for-service beneficiaries obtain outpatient prescription drug coverage outside of Medicare Part D, including Part D data in the MSPB measure would incorrectly indicate higher costs for these beneficiaries compared to others. We are considering possible approaches to payment-standardizing and operationalizing Part D costs. Regarding the comments related to the MSPB's risk adjustment methodology, we addressed similar comments in the IPPS/LTCH Final Rule and refer readers to that discussion (77 FR 53586 through 53588).

We did not receive any comments on our proposed regulation text changes at § 414.1235 or § 414.1260(b)(1)(i) and are, therefore, finalizing the proposed changes without modification.

Attribution of the MSPB measure to physician groups. In the CY 2014 PFS proposed rule, we proposed to attribute an MSPB episode to a group of physicians subject to the value-based payment modifier (as identified by a single TIN), when any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure

during the performance period for the applicable calendar year payment adjustment period. Thus, the same index admission and MSPB episode could be attributed to more than one group of physicians.

We stated that attribution of the MSPB episode to all groups of physicians from which an eligible professional submits a Part B claim for a service rendered during the hospitalization is the best way to assign responsibility for, and encourage greater coordination of, care furnished to Medicare beneficiaries who are hospitalized. We stated that, based on CY 2011 claims data, the proposed approach would enable approximately 11,419 groups of physicians with at least 10 eligible professionals to have an MSPB measure score included in their cost composite (78 FR 43494). We noted that many of these groups would otherwise not receive a cost composite score, because they do not provide the requisite primary care services of the five annual total per capita cost measures and, therefore, are not attributed beneficiaries. We stated that our proposed approach incentivizes hospitals and physicians to furnish efficient, effective care during a hospitalization and to coordinate post-discharge care to avoid unnecessary services and preventable readmissions. Further, we believe that this attribution approach fosters shared accountability between hospitals and physicians for the care they furnish to Medicare beneficiaries who are hospitalized. We proposed to add a new paragraph (b) to § 414.1240 to indicate that a MSPB episode would be attributed to a group of physicians subject to the value-based payment modifier if any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Groups of physicians would have a Medicare Spending per Beneficiary measure score included in their cost composite based on the proposed attribution methodology for the MSPB.

In the CY 2014 PFS proposed rule, we also sought comment on the alternative MSPB measure attribution approaches. We considered attributing an MSPB episode to a physician group when any eligible professional in the group billed a Part B claim for a service rendered at any time during the Medicare Spending per Beneficiary episode (that is, from 3 days prior to an index admission through 30 days post-discharge). We stated that this attribution approach would place an even stronger emphasis on shared accountability for care provided to Medicare beneficiaries who are hospitalized, both during and after their hospitalization. Based on 2011 claims data, we estimate that this attribution approach would enable an additional 3,017 groups of physicians with 10 or more eligible professionals to receive an MSPB measure performance rate for inclusion in the cost composite, as compared to our proposed attribution approach which considers only those eligible professionals who bill a Part B claim during the index admission. As with our proposed approach, the same index admission and MSPB episode could be attributed to more than one group of physicians under this alternative approach. We welcomed public comment on the alternative attribution approach under which we would attribute an MSPB episode to a physician group if any eligible professional in the group billed a Part B service during the 3 days prior to an index admission through 30 days post hospital discharge.

We also considered two alternative methods which would attribute each MSPB episode to a single physician group. The MSPB episode could be attributed solely to the group of physicians that provided the plurality of Part B services either: (1) during the entire MSPB episode (that is, from three days prior to an index admission through 30 days post discharge); or (2) during the index admission only. We wish to clarify the explanation of ''plurality'' of services that we provided in the proposed rule. By ''plurality,'' of services, we mean the highest total Medicare allowed amount for Part B services billed by any group of physicians who provided Part B services during a given portion of an MSPB episode (either the full episode or the index admission only). The group of physicians need not have billed the majority of the charges allowed by Medicare for Part B services furnished during a given portion of an episode, but rather the group's total allowed charges must be greater than any other group of physicians for that portion of the episode. These methods are single attribution approaches, unlike our proposal which is a multi-attribution approach.

Using 2011 claims, we analyzed the number of TINs, comprised of 10 or more eligible professionals, that would be attributed an MSPB measure rate under these alternative attribution methods given a minimum of 20 MSPB episodes required. Our analyses revealed that 7,799 TINs (out of approximately 17,000 TINs) would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the group of physicians that provided the plurality of Medicare Part B services during the entire MSPB episode. This represents a 46 percent decrease in the number of TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the entire episode. Our analysis also showed that 7,582 TINs would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the physician group that billed the plurality of Medicare Part B payments during the index admission. This represents a 34 percent decrease in the TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the index admission.

In the proposed rule, we explained that we considered these two single attribution methods because they represent methods to identify groups of physicians that were ''most responsible'' for the Part B Medicare payments made during the episode. We did not propose these methods, because we believed our proposed multiple attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during a hospitalization. We stated our belief that our proposed attribution approach is further supported by the higher number of TINs that will be able to receive an MSPB measure rate under that methodology. We solicited comment, however, on these two alternative single attribution approaches we considered: Attributing an MSPB episode to the group of physicians that provided the plurality of Part B services billed either during the entire MSPB episode or during the index admission only.

In the proposed rule, we also explained two versions of a ''hybrid'' attribution method we considered. This methodology would attribute MSPB episodes to all TINs from which an eligible professional provided services representing at least 35 percent of the total Medicare Part B payments made either: (1) during the entire MSPB episode (that is, from three days prior to an index admission through 30 days post discharge); or (2) during the index admission only. This alternative could result in multiple attribution, if two eligible professionals from different TINs each provided services representing at least 35 percent of the Part B Medicare payments during one of the episode portions described above (either the full episode or during the

index admission only). The rationale for this attribution approach is that it ensures that the MSPB measure would be attributed to a group of physicians who had responsibility for a significant portion of the Medicare beneficiary's care during a given portion of the MSPB episode. We did not propose this alternative, because we believed that our proposed attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during and after a hospitalization. We welcomed public comment on this alternative attribution approach based on provision of services representing at least 35 percent of Medicare Part B payments made either during the entire MSPB episode or during the index admission only.

The following is a summary of the comments we received regarding the proposed attribution method and alternative methods.

Comment: One commenter tentatively supported our proposal to attribute MSPB episodes to any physician group from which an eligible professional billed a Part B service during an index admission for the MSPB measure. A few commenters stated that they would prefer either single attribution based on the plurality of Part B services during the hospital stay or attribution based on the ''hybrid'' approach of attributing to any group from which an eligible professional provided at least 35 percent of the Part B services billed during the hospital stay. One commenter supported attribution based either on plurality of Part B services provided during the hospital stay or on a hybrid attribution during either the hospital stay or the entire episode. The majority of commenters stated that they would prefer attribution to a single physician group that provided the plurality of Part B services during the hospital stay. The commenters expressed their belief that our proposed attribution to any physician group from which an eligible professional billed a Part B claim during the index admission or episode was too broad, stating that it would not recognize physician groups' varying degrees of involvement in the patient's care during the episode, that it would not incentivize coordination of care, that the physician group to which the episode is attributed should have a minimum level of association with the patient's care, and that further analysis was needed before adopting such a broad attribution approach. One commenter expressed concern that attribution could inadvertently penalize inpatient physicians (for example, hospitalists) for costs beyond their control such as those occurring in the post-acute and outpatient settings or those incurred by specialists due to inadequate primary care. One commenter asked that we ensure that calculations used to specifically allocate costs associated with physician care versus care provided for the same patient in other settings or by other physicians/specialists are calculated and attributed accurately. One commenter stated that the measure could routinely penalize physicians whose practices focus on care settings such as nursing home or home care. One commenter stated that attribution should not be based on plurality of E&M services, and one commenter asked for clarification on how the measure would be attributed to groups that span a state or multiple regional hospitals.

Response: After considering the comments we received, we have decided not to finalize the attribution methodology that we proposed and instead will finalize the alternative, single attribution methodology that we considered, wherein an MSPB episode is attributed to the physician group (as identified by the Tax Identification Number) that furnished the plurality of Part B services during the index admission. This approach was the one most favored by commenters. This approach recognizes physician groups' varying degrees of involvement in the patient's care during the episode, incentivizes coordination of care, and helps ensure that the physician group to which the episode is attributed has a minimum level of association with the patient's care. We are finalizing this policy in appreciation of the commenters' concern that the group to which an episode is attributed should have been involved in a significant portion of the beneficiary's care. The hospital and the physician group providing the plurality of care during the hospitalization will be best able to coordinate care and discharge and reduce fragmentation and unnecessary service provision. We believe this approach addresses commenters' concerns that a specialist might be attributed an episode for which they were not primarily responsible. We also prefer this attribution approach to one in which there is a set minimum level of involvement (such as the ''hybrid'' 35 percent approach we considered), because such an alternative attribution approach could result in some episodes not being attributed to any physician group, because the groups with the plurality of care did not reach the minimum percentage of care (for example, 30 percent). We believe that omitting such episodes from the measure would be counter to our interest in incentivizing a team approach to care provision for the beneficiaries with the most complicated cases.

We do not intend to attribute portions of an MSPB episode to different physician groups depending on the setting in which the care was provided, as suggested by one commenter. The MSPB measure is not constructed in that manner. Rather, it is attributed to an entity that is responsible for provision of a significant portion of the beneficiary's care and is capable of improving the efficiency of care throughout the episode. We do not believe the plurality of care during the stay approach to attribution will have a disproportionately adverse effect on those physician groups involved primarily in provision of home health or skilled nursing facility care, because the physician whose group is attributed the episode must have provided more in-hospital care than any other physician. We wish to clarify that attribution of the MSPB measure would not be based on plurality of E&M services, but on plurality of all Part B services furnished during the index admission. In the case of a large physician group spanning multiple regions, the same policy would apply and the episode would be attributed to the TIN that billed the plurality of Part B services during the index admission. We appreciate the commenters' request for additional analysis of the effect of the attribution options we considered. As described in the proposed rule, we discussed the differences in the number of TINs that would receive an MSPB measure rate using a single attribution methodology based on plurality of care during the index admission, as compared to the number of TINs that would receive an MSPB measure rate under our proposed multiple attribution approach. We conducted additional analyses on the application of a minimum percentage of Medicare allowed charges that a physician group must have billed in order to be attributed an episode. As compared to a single attribution based on plurality with no minimum percentage, a multiple attribution approach requiring a group to have billed at least 35 percent of Medicare allowed charges resulted in a decrease from 7,582 attributed TINs to 7,389 attributed TINs, a decrease of 2.5 percent. This reduction is minimal, because while the floor precludes attribution of some episodes, multiple attribution allows some episodes to be attributed to more than one TIN. We found minimal difference in the number

of TINs receiving an MSPB measure rate under the single attribution based on plurality and the multiple attribution based on a minimum 35 percent of charges approaches. Since imposing a minimum floor such as 35 percent of charges would lead to having un-attributed MSPB episodes that are not supported by these findings, we are finalizing the attribution approach recommended by the majority of commenters—a single attribution based on plurality of Part B services during the hospital stay with no floor. As stated previously, we believe that attributing the MSPB episode to the physician group that provided the plurality of care during the hospitalization is the best approach to recognizing the group of physicians in the best position to affect improved coordination, decrease fragmentation, and control Medicare expenditures. We will monitor and examine the effects of this attribution approach as we implement the MSPB measure and may consider changes to this policy through future rulemaking.

Reliability standard for the Medicare Spending per Beneficiary measure for the value-based payment modifier. We proposed that a group of physicians would have to be attributed a minimum of 20 MSPB episodes during the performance period to have their performance on this measure included in the value-based payment modifier cost composite. Table 86 shows the MSPB measure's reliability at various minimum numbers of episodes for all Medicare-enrolled TINs with at least one EP (not just TINs of 10 or more eligible professionals) from May 2011 through December 2011. (We note that Table 86 does not consider the specialty adjustment that we are finalizing in section III.K.4.g.2. below.) In this context, reliability is defined as the extent to which variation in the measure's performance rate is due to variation in the cost of services furnished by groups of physicians rather than random variation due to the sample of cases observed. Potential reliability values (known in statistics as the correlation coefficient) range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in the difference in performance across groups of physicians and is not due to random variation. Generally, reliabilities in the 0.40–0.70 range are often considered moderate and values greater than 0.70 high.

TABLE 86—RELIABILITY OF MEDICARE SPENDING PER BENEFICIARY MEASURE FOR ALL TINS WITH AT LEAST ONE ELIGIBLE PROFESSIONAL

[May 2011–December 2011]

MSPB Episodes attributed	Number of TINs	Percent of TINs	Mean risk-adjusted standardized cost per MSPB episode	Average reliability
1–9	59,419	47	$20,493	0.65
10–19	12,332	10	21,260	0.79
20–29	7,774	6	21,225	0.83
30–39	5,839	5	21,340	0.85
40–49	4,511	4	21,324	0.87
50–99	12,648	10	21,353	0.89
100–124	3,702	3	21,403	0.91
125–149	2,761	2	21,342	0.92
150–174	2,134	2	21,316	0.93
175–199	1,673	1	21,119	0.93
200+	14,933	12	20,562	0.96

We also considered a minimum number of 10 episodes. The advantage of this lower minimum number is that it would enable us to calculate the MSPB measure for an additional 12,332 physician groups once we apply the value-based payment modifier to all physicians and groups of physicians. With a minimum of 10 cases, the measure is still very reliable, as illustrated in the Table 86. We proposed the minimum of 20 cases for initial implementation of this measure in the cost composite beginning with the CY 2016 value-based payment modifier because it strikes a balance between maintaining high reliability and including a large number of physician groups. We noted that this reliability standard we proposed is the same one we adopted in the CY 2013 PFS final rule with comment period that applies to quality and cost measures used in the value-based payment modifier (77 FR 69323). We welcomed public comment on our proposed minimum of 20 episodes for inclusion of the Medicare Spending per Beneficiary measure in the cost composite for the value-based payment modifier and on the alternative 10 episode minimum that we considered.

Comment: We received several comments on our proposed 20 episode minimum and the alternative 10 episode minimum we considered. Several commenters supported a minimum of 10 cases, in order to enable more groups to receive an MSPB measure performance rate for inclusion in the cost composite. These commenters noted that the MSPB measure is still very reliable at 0.70 with a minimum of 10 cases. Several commenters also stated that the proposed minimum of 20 cases was appropriate. One commenter suggested a minimum of 30 cases would be appropriate.

Response: We agree that the MSPB measure is still very reliable with a minimum of 10 cases, and we recognize that increasing the cost composite measure set for physician groups is a positive outcome of reducing the case minimum from our proposed minimum of 20. We believe that, because the measure is new, and a minimum of 20 cases still allows a substantial number of physician groups to have an MSPB measure rate in their cost composites, the proposed minimum of 20 cases is most appropriate for this measure's initial inclusion in the value-based payment modifier. We believe that a minimum of 20 cases strikes a good balance between preserving high reliability and maximizing the number of physician groups that receive an MSPB measure rate as part of their cost composite. After consideration of all public comments on the inclusion of the MSPB measure in the cost composite for the CY 2016 physician value-based payment modifier, we are finalizing the following policies:

We proposed a slightly revised calculation for inclusion of the MSPB measure in the value-based payment modifier. We proposed not to convert the MSPB amount to a ratio as is done to compute a hospital's MSPB measure under the Hospital IQR and VBP Programs, but rather to use the MSPB amount as the measure's performance rate.

We are finalizing inclusion of the MSPB measure as proposed in the cost composite beginning with the CY 2016 value-based payment modifier, with a CY 2014 performance period. As we proposed, we will use the MSPB amount as the measure's performance rate rather than converting it to a ratio as is done under the Hospital IQR and VBP Programs.

We are finalizing that the MSPB measure will be added to the total per capita costs for all attributed beneficiaries domain and equally weighted with the total per capita cost measure. It will not be added to the total per capita costs for all attributed beneficiaries with specific conditions domain.

We are finalizing the method under which an MSPB episode will be attributed to a single group of physicians that provides the plurality of Part B services during the index admission, for the purpose of calculating that group's MSPB measure rate.

We are finalizing a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a physician group's cost composite.

We are finalizing regulation text as proposed at § 414.1235 and § 414.1260(b)(1)(i).

We are finalizing the regulation text at § 414.1240(b) to read: For the MSPB measure, an MSPB episode is attributed to the group of physicians subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.

g. Refinements to the Cost Measure Composite Methodology

(1) Average Cost Designations in Certain Circumstances

In the CY 2013 PFS final rule with comment period (77 FR 69322), we established a policy to create a cost composite for each group of physicians subject to the value-based payment modifier that includes five payment-standardized and risk-adjusted annual per capita cost measures. To calculate each group's per capita cost measures, we first attribute beneficiaries to the group of physicians. We attribute beneficiaries using a two-step attribution methodology that is used for the Medicare Shared Savings Program and the PQRS GPRO and that focuses on the delivery of primary care services (77 FR 69320). We have observed that groups of physicians that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries and, thus, we are unable to calculate reliable cost measures for those groups of physicians (77 FR 69323). Given this development, we proposed that, to the extent that we are unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the value-based payment modifier and thus are unable to calculate any of the cost measures with at least 20 cases, the group of physicians' cost composite score would be classified as ''average'' under the quality-tiering methodology. We believe this policy is reasonable because we would have insufficient information on which to classify the group of physicians' costs as ''high'' or ''low'' under the quality-tiering methodology. Moreover, we believe that to the extent a group of physicians' quality composite is classified as ''high'' or ''low,'' the groups of physicians' value-based payment modifier should reflect that classification. Accordingly, we proposed to add a new paragraph at § 414.1270 to reflect this proposal that groups of physicians in Category 1 for which we attribute fewer than 20 cases to calculate any cost measure would have their cost composite classified as ''average'' cost. We solicited comment on this proposal. The following is summary of the comments we received regarding this proposal.

Comment: The majority of comments received on this proposal were from commenters who supported our proposal and agreed that this was a reasonable proposal because CMS would have insufficient information to classify the group's cost as high or low, and other assumptions would be unfair to practices attributed fewer than 20 beneficiaries. The few commenters who opposed the proposal believed that it would unfairly advantage physician groups that have unnecessarily high costs and disadvantage providers who provided exceptional care at very low costs. One of the two commenters who opposed this proposal suggested that CMS could remove costs from the value-based payment modifier determination for such groups.

Response: We continue to believe that groups that are attributed fewer than the minimum case size of 20 beneficiaries would not allow for the calculation of reliable cost measures. We are concerned that not classifying the group as average when it has fewer than 20 attributed beneficiaries would increase the likelihood that its cost measures could fluctuate greatly from year to year, so we disagree with some of the commenters who stated that it would unfairly advantage or disadvantage different physician groups.

After consideration of the comments received, we are finalizing our proposal and adding a new paragraph at § 414.1270 to reflect the proposal that groups of physicians in Category 1 for which we attribute fewer than 20 cases to calculate any cost measure have their cost composite classified as ''average'' cost.

Comment: Some commenters expressed or reiterated previously stated concerns about CMS' use of total per capita cost measures for the value-based payment modifier. In the CY 2012 PFS final rule with comment period (76 FR 73434), we finalized the use of total per capita cost measures and per capita cost measures for beneficiaries with four chronic conditions (chronic obstructive pulmonary disease, coronary artery disease, diabetes, and heart failure) in the value-based payment modifier. In the CY 2013 PFS final rule with comment period (77 FR 69318), we finalized the use of the CMS Hierarchical Condition Category (HCC) model to risk adjust these total per capita cost measures in the value-based payment modifier. Arguments against the total per capita cost measures that commenters raised in response to the CY 2014 PFS proposed rule included that the cost measures reflect the total amount billed per patient by Medicare overall rather than the amount billed per patient by just the medical group, may not be appropriate for some specialists, and was not developed for nor tested in physician practices. Some commenters expressed concerns that the risk adjustment used in the total per capita cost measures is inadequate, either because of concerns about the CMS Hierarchical Condition Category (HCC) model or because the risk adjustment method lacked adjusters for physicians that tend to treat non-compliant patients. One commenter requested that CMS ensure that the expenditures are adjusted for geographic differences in input costs.

Other concerns raised by commenters included the potential for groups to shift

drug costs from Part B to Part D, since Part D is not included in the cost measure. Several other commenters requested that CMS not use total per capita cost measures in the value-based modifier until we have developed and tested more focused episode-based cost measures. One commenter expressed concern about potential problems in shifting from the ICD–9–CM to the ICD–10–CM system, since the HCC model assigns prior year ICD–9–CM diagnosis codes to 70 high cost clinical conditions.

Response: We continue to believe that the total per capita cost measures provide useful information and are appropriate to incent physician groups who are in a good position to oversee annual costs to do so. We refer readers to previous CMS responses to a number of concerns raised again this year (about, for example, the appropriateness of the total per capita cost measure for some specialists and the adequacy of the risk adjustment used for the measure) that were discussed in the CY 2012 (76 FR 73433 through 73436) and CY 2013 PFS final rules (77 FR 69315 through 69318). We also reiterate that the total per capita cost measures are payment-standardized (77 FR 69316 through 69317), which removes regional or local price differences that may lead to cost variation that a physician group cannot influence. We are aware of the commenters' concerns with total per capita cost measures and the risk adjustment approach, and we will monitor the situation as we implement the value-based payment modifier. If warranted, we will propose modifications to the total per capita cost measures and the risk adjustment approach in future rulemaking.

Regarding the potential to shift drug costs from Part B to Part D, we will take this comment into consideration as we monitor the impacts when the value-based payment modifier is implemented. Regarding testing episode-based cost measures, we have not yet proposed using output from the CMS episode grouper—that is currently under development and discussed in the Physician Feedback Program section (see section III.K.5.c.)—in the value-based payment modifier. We will consider proposing to include episode-based cost measures in future years' value-based payment modifiers (beyond 2016) through future rulemaking after we have thoroughly tested the CMS episode grouper and groups have seen their performance on them. We believe, however, that total per capita cost is a useful measure of total volume of healthcare services to Medicare beneficiaries and encourages shared accountability for beneficiary care and we have shared the results of this measure with all groups of 25 or more eligible professionals. Therefore, we disagree with the commenters who are calling for a delay in the use of the total per capita cost measure in the value-based payment modifier. Finally, we are studying the impacts of the planned ICD–9 to ICD–10 conversion across the Medicare program.

Comment: Some commenters expressed concerns about CMS using cost measures that have not been endorsed by the National Quality Forum (NQF), while others stated agreement with some of the concerns about the total per capita cost measure that were raised by the NQF Cost and Resource Use Committee (for example, concerns about the total per capita cost measure's reliability, validity, and usability, as well as lack of inclusion of Part D costs in the measure). One commenter expressed appreciation to CMS for taking a thoughtful approach to the implementation of the cost measures (via NQF submission).

Response: We submitted the total per capita cost measure for NQF endorsement in January 2013. (For further information, please see materials related to the submission of NQF candidate measure #2165 (Payment-Standardized Total Per Capita Cost Measure for Medicare Fee-for-Service (FFS) Beneficiaries) in the Cost and Resource Use 2012: Phase 1 section of the NQF Web site—*http://www.qualityforum.org/Projects/c-d/Cost_and_Resource_2012_Phases_1_and_2/Cost_and_Resource_Use_2012_Phase_1.aspx#t=2&s=&p=5%7C.*) In the final voting in September 2013, the NQF Cost and Resource Use Committee narrowly voted against the measure by a count of 12 in support and 13 in opposition. We anticipate addressing the Committee's concerns in future rulemaking, especially regarding our attribution model and how best to incorporate socioeconomic status in our measure, after the NQF provides additional guidance regarding risk adjustment for resource use measures.

Consistent with the policy we established in the CY 2013 PFS final rule, we will continue to use the total per capita cost measures in the value-based payment modifier, and we will continue to evaluate the measure methodology and update the measure as appropriate.

(2) Cost Composite Benchmarking and Peer Groups

Once we calculate the cost measures for each group of physicians subject to the value-based payment modifier, we create the cost composite by calculating a standardized score for each cost measure and then placing the measures into one of two equally weighted domains: (1) the total per capita costs for all attributed beneficiaries domain; and (2) the total per capita costs for attributed beneficiaries with specific conditions domain. This standardized score is referred to in statistical terms as a Z-score. To arrive at the standardized score for each cost measure, we compare the performance for each group's cost measures to the benchmark (national mean) of other groups subject to the value-based payment modifier (peer group) for the same performance year. Specifically, we calculate the benchmark for each cost measure as the national mean of the performance rates among all groups of physicians to which beneficiaries are attributed and that are subject to the value-based payment modifier.

Using 2011 claims data, we examined the distribution of the overall total per capita cost measure among all groups of physicians with one or more eligible professionals to determine whether comparisons at the group level would be appropriate once we apply the value-based payment modifier to smaller groups of physicians and solo practitioners. We found that our current peer grouping methodology could have varied impacts on groups of physicians that are comprised of different physician specialties. This result occurs because the peer group for the per capita cost benchmarks is based on a national mean calculated among all groups of physicians subject to the value modifier rather than determined more narrowly (for example, within a physician specialty).

To address this issue beginning with the CY 2016 value-based payment modifier, we considered two methods that account for the group practice's specialty composition so that our quality-tiering methodology produces fair peer group comparisons and, ultimately, correctly ranks group of physicians based on actual performance. Taking account of physician specialties in making cost comparisons is similar to the approach we have used in the CY 2010 and CY 2011 Quality and Resource Use Reports (QRURs) for individual physicians in which we made cost comparisons at the individual physician specialty level.

The first method, ''specialty adjustment,'' accounts for the specialty composition of the group prior to computing the standardized score for each cost measure. This method enables us to develop comparable benchmarks for the risk-adjusted cost measures

against which to evaluate groups of physicians of smaller size who often have fewer or single specialty composition. More specifically, this method adjusts the standardized score methodology to account for a group's specialty composition using three steps:

Step 1: Create a specialty-specific expected cost based on the national average for each cost measure (referred to as the ''national specialty-specific expected costs''). To do so, we attribute beneficiaries to a group using the plurality of primary care services methodology that we finalized in the CY 2013 PFS final rule with comment period (77 FR 69316). For each specialty, we calculate the average cost of beneficiaries attributed to groups of physicians with that specialty, weighted by the number of EPs in each group.

Step 2: Calculate the ''specialty-adjusted expected cost'' for each group of physicians by weighting the national specialty-specific expected costs by the group's specialty composition of Part B payments. That is, the specialty-adjusted expected cost for each group is the weighted average of the national specialty-specific expected cost of all the specialties in the group, where the weights are each specialty's proportion of the group's Part B payments. The Part B payments for each specialty are determined based on the payments to each EP in the group, and each EP is identified with one specialty based on its claims.

Step 3: Divide the total per capita cost by the specialty-adjusted expected cost, and multiply this ratio by the national average per capita cost so that we can convert this ratio to a dollar amount (referred to as the ''specialty-adjusted total per capita cost'') that can then be used in the standardized (Z-) score to determine whether a group can be classified as high cost, low cost, or average.

Below, we illustrate the three steps of the specialty adjustment to the standardized score with an example. Assume for simplicity that only two TINs and two specialties exist: TIN 1 and TIN 2, and Specialty A and Specialty B. For this example, assume that the total per capita costs and specialty shares are as shown in Table 87.

TABLE 87—EXAMPLE OF CALCULATING SPECIALTY-ADJUSTED TOTAL PER CAPITA COST: ASSUMPTIONS

TIN	Risk-adjusted per capita cost	Number of attributed beneficiaries	Number of EPs in TIN by specialty type A or B	Specialty share of EPs in TIN	Specialty share of part B payments in TIN
TIN 1	$12,000	1,500	A: 10; B: 30	A: 25%; B: 75%	A: 35%; B: 65%
TIN 2	8,000	2,000	A: 21; B: 39	A: 35%; B: 65%	A: 60%; B: 40%

Step 1: To compute the national specialty-specific expected cost for a specialty across all TINs, we first calculate the numerator, which is the product of each TIN's total per capita cost times its weight (the number of attributed beneficiaries times that specialty's share of the TIN's EPs times the number of EPs of that specialty in that TIN), summed across all TINs. This sum is divided by the denominator, which is the sum across all TINs of the same weights that were used in the numerator. For this example, the national specialty-specific expected cost for Specialty A is ($12,000 * 1,500 * 25%*10 + $8,000 * 2,000 * 35%*21)/(1,500 * 25%*10 + 2,000 * 35%*21) = $8,813. Similarly, the national specialty-specific expected cost for Specialty B is ($12,000 * 1,500 * 75%*30 + $8,000 * 2,000 * 65%*39)/(1,500 * 75%*30 + 2,000 * 65%*39) = $9,599.

National Specialty-Specific Expected Cost, by Specialty (Step 1)

Specialty A: $8,813
Specialty B: $9,599

Step 2: To calculate the specialty-adjusted expected cost for each group (TIN), we would multiply the above national specialty-specific expected costs by each group's proportion of specialty-specific Part B payments. For each TIN, we compute the product of the TIN's proportion of specialty-specific Part B payments, summed across all specialty types of the TIN. In our example, the specialty-adjusted expected cost for TIN 1 would be computed as 35% * $8,813 + 65% * $9,599 = $9,324. Similarly, the specialty-adjusted expected cost for TIN 2 would be 60% * $8,813 + 40% *$9,599 = $9,127.

Specialty-Adjusted Expected Cost, by TIN (Step 2)

TIN 1: $9,324

TIN 2: $9,127

Step 3: We divide the total per capita cost by the specialty-adjusted expected cost and multiply this ratio by the national average per capita cost, to convert this ratio to a dollar amount. Assuming the national average per capita cost is $9,714, we can compute the specialty-adjusted total per capita cost for each TIN, as shown in Table 88.

TABLE 88—EXAMPLE OF CALCULATING SPECIALTY-ADJUSTED TOTAL PER CAPITA COST: CALCULATIONS

Column	A	B	C	D
TIN	Total per capita cost	Specialty-adjusted expected cost	National average per capita cost	Specialty-adjusted total per capita cost: ((column A/column B) * column C)
TIN 1	$12,000	$9,324	$9,714	$12,502
TIN 2	8,000	9,127	9,714	8,514

The figure in the rightmost column (column D) is the specialty-adjusted total per capita cost that is used to compute a group's standardized (Z-) score. As can be seen, the specialty-adjusted total per capita cost for use in the standardized score is $12,502 for TIN 1 and $8,514 for TIN 2.

To illustrate the impact of the specialty adjustment methodology, we examined the distribution, by specialty, of the overall specialty-adjusted total

annual per capita cost measure based on 2011 claims for group of physicians with 1 or more eligible professionals. Please see Table 66 of the CY 2014 proposed rule (78 FR 43498 through 43499) for the results of this analysis.

Under this methodology, we perform this specialty adjustment prior to computing the standardized score for all six cost measures included in the value-based payment modifier: the total per capita cost measure, the four total per capita cost measures for beneficiaries with specific conditions, and the MSPB measure. The specialty adjustment for the four condition-specific total per capita cost measures is identical to the total per capita cost measure that was described above. The specialty adjustment for the MSPB cost measure is analogous to that described above for the total per capita cost measure, except that ''number of beneficiaries'' is replaced with ''number of episodes'' and ''per capita cost'' is replaced with ''per episode cost.'' Thus, each cost measure will have its own set of specialty-specific expected costs.

We considered and tested a second method, ''comparability peer grouping,'' which constructs peer groups for each physician group practice by identifying group practices with the nearest comparable specialty mix.[5] Under this approach, two group practices would be considered to have the same specialty mix if the share of physicians of each specialty is within a defined range for both group practices. Group practices that had a specialty mix more comparable to the practice's own mix would receive greater weight in the peer group. Among the identified peers sharing the same specialty mix, those with the most cases would receive the greatest weight.

We stated in the proposed rule that, on balance, we believe that the first method, the specialty benchmarking method, is preferable to account for the specialty composition of the group of physicians when making peer group comparisons and creating the standardized score for the cost measures for the value-based payment modifier. We also stated that this methodology allows us to apply the value-based payment modifier to smaller size groups and solo practitioners. This methodology creates one national benchmark for each cost measure. Moreover, all groups of physicians (regardless of size) are assessed against that benchmark in creating the group of physicians' standardized score. Although the calculations discussed above may be very detailed, they are transparent and we can provide each group of physicians with information on how its costs were benchmarked in its Quality and Resource Use Report.

By contrast, the second method, comparability peer grouping, would require us to develop a transparent way to define which groups of physicians are similar enough to be included in each group of physicians' peer group. This approach also creates a different benchmark for each group of physicians, which may make it more difficult for groups of physicians to understand how their costs are benchmarked.

Given these considerations, we proposed to use the first method, the specialty benchmarking method, to create the standardized score for each group's cost measures beginning with the CY 2016 value-based payment modifier. Accordingly, we proposed to amend our regulations at § 414.1255 to include this policy in our cost composite methodology. We solicited comment on our proposals, including comments on ways to streamline or enhance the calculation mechanics and to make the specialty adjustments more transparent and easily understood. We also solicited comment on the alternative method, the comparability peer grouping method. We proposed to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims. We understand that many physicians believe our current specialty designations may mask sub-specialist care furnished. We note that the procedures for obtaining a CMS specialty code are available at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html*. The following is summary of the comments we received regarding these proposals.

Comment: The majority of commenters supported our approach to consider physician specialty in our cost benchmarking. For example, one commenter suggested it was a significant improvement over our current methodology. Another commenter supported the refinement of the cost measure benchmarking methodology to reflect the full range of practitioners. A number of commenters expressed support for CMS refining the cost measure benchmarking methodology to account for a physician's specialty.

A number of the commenters who supported the proposal, as well as several others who neither supported nor opposed the proposal, suggested that CMS study further the specialty adjustment to determine the impacts and potential unintended consequences prior to its inclusion so that future refinements can be made if necessary. Some commenters also asked that CMS continue to consider opportunities to compare physicians based on the type of patients they are seeing. A number of commenters urged CMS to use more subspecialty designations in the approach to adequately account for subspecialties and allow fair benchmark comparisons of cost provided by specialists. Several commenters suggested that we assign specialty designations based on a claims analysis to identify the services most typically provided by the individual (that is, the top 15 services the provider renders based on submitted claims) and assign their specialty based on the care they are most frequently providing. Another commenter suggested that we include an adjustment for site of service (for example, nursing home or long-term care facility).

Several commenters expressed concern that the CMS' proposed approach to specialty adjustment could result in a ''high cost'' designation for about 15 percent of some specialties (geriatricians, geriatric psychiatrists, neurosurgeons, medical and surgical oncologists), which could suggest a problem in the methodology.

While most commenters supported the specialty adjustment approach over the comparability peer grouping approach, several commenters preferred the comparability peer grouping approach. One commenter indicated that they did not have sufficient information on the criteria that CMS would use to determine comparable peer groups if the approach were implemented. Although more commenters who expressed a preference indicated that the specialty adjustment approach was more transparent, several commenters stated that the comparability peer grouping method would likely achieve greater transparency of performance, although the specialty adjustment method might be simpler to calculate. The same commenters recommended further study by CMS of the comparability peer grouping approach.

Response: We agree that the proposal is a significant improvement over our current methodology. We believe that the credibility of the quality-tiering approach depends on accurate comparisons among physicians to determine those physicians that are members of high- and low-cost groups.

[5] For a description of this type of method, see, for example, Margaret M. Byrne, et al., Method to Develop Health Care Peer Groups for Quality and Financial Comparisons Across Hospitals. April 2009. HSR: Health Services Research 44:2, Part I: 577–592.

We proposed this method to adjust our benchmarking approach for all cost measures to create more comparable peer groups through developing a benchmark for each group based on the specialty composition of the group. We believe that this proposal improves upon our cost benchmark such that it would be appropriate once we apply the value-based payment modifier to smaller groups and solo practitioners.

We also believe that the specialty adjustment approach is adaptable to comparing physicians in solo practices, which is important because in 2017 we are required to apply the value-based payment modifier to all physicians and groups of physicians. Although we received a number of comments from sub-specialists about the lack of granularity among the available CMS physician specialties, we believe this approach is better than relying on group size alone. We also will explore ways to explain to sub-specialists the processes that we have in place to obtain a new or keep their CMS specialty designation current, and we encourage all physicians to periodically review and keep their Medicare enrollment information current including specialty designations.

We agree that an adjustment for site of service (for example, nursing home or long-term care facility) is worthwhile to consider, and will take this comment into account as a potential refinement for further exploration.

Regarding the concern that our proposed approach to specialty adjustment could result in a ''high cost'' designation for about 15 percent of some specialists, we would like to clarify the data on Table 66 of the proposed rule (78 FR 43498 through 43499). Table 66 provides the percentage of physicians practicing in groups with one or more eligible professionals with at least 20 beneficiaries and does not represent all physicians within that specialty. Therefore, it is incorrect to state, for example, that Table 66 (Percentage of Physician Practicing in Groups with 1 or more Eligible Professionals with at Least 20 Beneficiaries, Classified by Cost), indicates that 14.9 percent of neurosurgeons would be classified as ''high cost.'' Rather, 14.9 percent of neurosurgeons practicing in groups with 1 or more eligible professionals with at least 20 beneficiaries attributed to the practice would be classified as ''high cost.''

We believe that the comparability peer group method would require too many assumptions to be a practical alternative to consider implementing in the near term. As a result, we believe that the comparability peer group method option would be less transparent than the specialty adjustment method. Although the specialty adjustment method process is somewhat computationally involved, the calculations are straightforward, and we believe that the method is transparent. We believe that it is not necessary to delay implementing the specialty adjustment method, but we do agree that it is important to monitor the impacts of the specialty adjustment method on physician groups as the method is implemented starting with the 2016 value-based payment modifier.

After consideration of the comments received and the reasons given previously, we are finalizing our proposal to use the specialty adjustment method to create the standardized score for each group's cost measures beginning with the CY 2016 value-based payment modifier. That is, we are refining our current peer group methodology to account for specialty mix using the specialty adjustment method. We also are finalizing our proposal to amend our regulations at § 414.1255 to include this policy in our cost composite methodology. Additionally, we are finalizing our proposal to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims.

5. Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries. In the CY 2014 PFS proposed rule (78 FR 43500) we described the 2011 group and individual QRURs, which were based on CY 2011 data that we made available to certain physicians and groups of physicians. These reports provided physicians and groups of physicians with comparative performance data (both quality and resource use) that can be used to improve quality and coordinate care furnished to Medicare FFS beneficiaries. We also noted that in May 2013, we provided supplemental QRURs to group report recipients that featured episode-based costs for care of pneumonia and several acute and chronic cardiac conditions. We derived these episode-based costs using the newly developed CMS Episode Grouper software required by section 1848(n)(9)(ii) of the Act.

a. CY 2012 Group Quality and Resource Use Reports Based on CY 2012 Data and Disseminated in CY 2013.

On September 16, 2013, we made available CY 2012 QRURs to 6,779 physician groups nationwide with 25 or more EPs. These reports covered approximately 400,000 physicians practicing in large medical groups. These reports were available eight and one-half months from the close of the performance period (December 31, 2012) and 5 months from the close of the quality data submission period (March 31, 2013)—timeframes that are generally consistent with reporting programs in the commercial sector. Not only did these reports provide comparative quality of care and cost information like in previous years, but they also previewed how the groups of physicians might fare under the value-based payment modifier. Thus, these reports were a ''first look'' at how the value-based payment modifier could affect their payment in the future. The QRURs provided groups of 100 or more EPs with quality-tiering information on 2012 data that they could use to decide whether to elect to be assessed under the quality-tiering approach that we adopted for the value-based payment modifier that will be applied in 2015, based on 2013 performance.

Additionally, and in response to feedback we received from prior year recipients of the QRURs, the CY 2012 QRURs contained detailed beneficiary-specific data on each group's attributed beneficiaries and their hospitalizations, and the group's associated eligible professionals. Complementing the CY 2012 QRURs are three downloadable drill down tables that provide information on each beneficiary attributed to the group and each eligible professional billing under the group's Taxpayer Identification Number (TIN). We have received very positive feedback from report recipients and expect to enhance the information we provide in future years.

Of the 6,779 physician groups nationwide with 25 or more EPs, 3,876 groups received full QRUR reports and 2,903 groups received an abbreviated report since they did not have any beneficiaries attributed to them or did not have at least 20 eligible cases for any quality or cost measure. These 2,903 groups had insufficient data on which to compute meaningful performance measures. Given the policies that we have adopted in this final rule with comment period, we anticipate that as long as a group of physicians participates in the Physician Quality Reporting System (PQRS) in 2014 and

meets the criteria to avoid the 2016 PQRS payment adjustment such that group is in Category 1 (see discussion above in section III.K.4.b.), we will be able to produce a complete QRUR, including their quality-tiering designation, in CY 2014 for most groups.

Highlights of major findings of these CY 2012 reports are as follows:

- Of the 3,876 groups for whom the quality or cost composite could be calculated based on 2012 data, over 80 percent of the groups (80.7 percent) are in the average quality and average cost tiers under the quality-tiering methodology, and thus, would not receive a payment adjustment. Approximately 8 percent of groups are in tiers that would receive an upward adjustment, and slightly less than 11 percent of groups are in tiers that would receive a downward adjustment. Among the groups eligible for an upward adjustment, 11 percent would receive an additional 1.0 percent incentive payment due to treating high-risk beneficiaries. Although we expect the results to change as physician groups understand our methodologies and seek to maximize their upward payment adjustment under the value-based payment modifier, these results are consistent with our approach to gradually implement the value-based payment modifier (see 2. Governing Principles for Physician Value-Based Payment Modifier Implementation), that is, to focus on adjusting payment for those groups that are outliers (both high and low performers).
- Groups with high quality scores performed better than groups with average and low quality scores consistently across each of the quality domains (or groupings of quality measures) as well as across the three quality outcomes measures; they also tended to have lower average cost composite scores.
- Beneficiaries that we attributed to a group of physicians received an average of five primary care services in 2012 of which, on average, 64.3 percent were provided by the group to which the beneficiary was attributed. These results suggest that our attribution approach attributes beneficiaries to those groups of physicians that deliver the majority of a beneficiary's care and are well positioned to oversee the beneficiaries' care.
- Reliability among the quality measures was generally strong, with the self-reported PQRS measures having the greatest average reliability. Average reliabilities for all PQRS measures were more than 0.80, indicating high reliability. We note that statistical reliability scores are represented on a continuum from zero and one, with scores closer to zero indicating lower reliability while scores closer to one indicate higher reliability. While there is no universally agreed upon minimum reliability threshold, reliability scores in the 0.40–0.70 range are often considered moderate and scores greater than 0.70 are considered high. In addition to the PQRS measures, we computed 14 quality indicators from data reported in Medicare administrative claims. The average reliability of the claims-based quality indicators was lower than for the PQRS quality measures but was still quite high with 8 of the 14 measures having average reliabilities above 0.70.
- The 2012 QRURs also reported on three administrative claims-based outcome measures. The QRURs contained each group practice's performance on measures of potentially avoidable hospitalizations for ambulatory care sensitive conditions (ACSCs). These Medicare claims-based measures were derived from Prevention Quality Indicators (PQIs) developed by the Agency for Healthcare Research and Quality (AHRQ). We reported on potentially avoidable hospitalizations for two composite measures of hospital admissions for acute and chronic ACSCs. The average reliability for both ACSC composite measures across all groups was higher than 0.70. CMS also reported on a medical group practice-specific all-cause 30-day rate of acute care hospital readmissions for beneficiaries discharged from an acute care or critical access hospital. Average reliability among the subset of groups of 100+ EPs was 0.48. We anticipate the reliability of this measure to increase as groups of physicians begin to focus on reducing unplanned readmissions.
- The QRURs include five cost-of-care measures derived from 2012 administrative claims data: total per capita costs and per capita costs for beneficiaries with four common chronic conditions: diabetes; heart failure; COPD; and CAD. The per capita (per beneficiary) cost measure assesses health care services for all Medicare FFS attributed beneficiaries and for those with chronic conditions. The measure includes all Medicare Part A and Part B costs during a calendar year and is price-standardized and risk-adjusted to account for any potential differences in costs among providers that result from circumstances beyond the physician's control. The risk adjustment process reduced the overall average per capita costs from $12,815 to $10,788 and compressed the range of groups' total per capita costs by 83 percent. Under our attribution rule, beneficiaries are attributed on the basis of the plurality of primary care services, to those medical group practices with the greatest potential to influence the quality and cost of care delivered to Medicare FFS beneficiaries. All group practices with 25 or more EPs achieved an average reliability score of 0.94 for the total per capita cost measure. For all groups, average reliabilities for the condition-specific cost measures ranged from 0.82 to 0.84. For larger groups with 100+ EPs, average reliability was higher for all beneficiaries (0.98), as well as for the condition-specific cost measures (0.94 for all measures).

We anticipate publicly releasing a full experience report of the CY 2012 QRURs that will include how quality-tiering would apply to groups of physicians to ensure stakeholders understand the methodologies of the value-based payment modifier. The report will be available on the Physician Feedback Program Web site.

b. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A)(ii) of the Act, as added by section 3003 of the Affordable Care Act, requires CMS to develop a Medicare episode grouper by January 1, 2012, and to include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper is software that organizes administrative claims data into episodes.

We have developed a CMS prototype episode grouper that classifies episodes into three categories: chronic; acute; and procedural. In the CY 2014 PFS Proposed Rule (78 FR 43502) we described the supplemental QRURs we made available to 54 large group practices in June 2013 to illustrate how the CMS Episode Grouper works and to illustrate the general approach to classifying episodes of care into these three categories. The Supplemental QRURs included episode-based costs for five clinical conditions (pneumonia, acute myocardial infarction (AMI), coronary artery disease, percutaneous coronary intervention (PCI), and coronary artery bypass graft (CABG)), which also were broken into 12 episode sub-types to account for various underlying clinical factors. We chose these episode types to gain experience with the prototype methodology of the CMS episode grouper in acute, chronic and procedural conditions.

We applied different attribution rules for each episode type (chronic, acute, or

procedural) and whether the episode included a hospitalization. We believe that it is critical to attribute an episode to the group of physicians that is in the best position to oversee the quality of care furnished and the resources used to furnish that care. For chronic episodes, attribution was based on outpatient E&M visits, because these conditions are best managed in an outpatient setting. For acute inpatient-based episodes, attribution was based on Part B Physician Fee Schedule allowed amounts during the inpatient stay or percent of inpatient E&M visits; for outpatient-based acute episodes, attribution was based on E&M visits during the episode. For procedural episodes, attribution is made to the group that includes the performing surgeon. For chronic and acute episodes, attribution required at least 35 percent of total allowed amounts or E&M visits, as applicable to the episode type. Episodes may be attributed to more than one group, although 85 percent of all episodes of any type were attributed to exactly one of the 54 medical group practices.

We also used a slightly different risk adjustment methodology to adjust the costs for the underlying risk factors for the beneficiaries with these episodes as compared to the total per capita cost measures that we have used in the CY 2012 QRURs. The CMS Episode Grouper used to generate the 2011 episode data adjusted costs for health and treatment history in the 6 months prior to the beginning of the episode. More specific risk adjusters include demographic factors (age, gender, and enrollment status), health status indicators (for example, medical condition categories from HCC model), and procedure indicators. We are continuing to examine ways to refine this approach as we develop further episode costs for additional clinical conditions.

The episodes we included in the reports had a high statistical reliability and showed a significant amount of variation across the groups and within the groups. From a reliability perspective, episodes had high or moderate reliability with six having a reliability of risk adjusted cost greater than 0.7 (range 0.78 for all AMI to 0.9 for coronary artery disease without AMI) and six between 0.5 and 0.7 (range 0.56 for PCI without AMI to 0.69 for AMI with PCI).

There also was variation among the groups' mean episode costs compared to the national mean. For four of the five conditions, about half of the groups had a mean episode cost that was above the national episode mean, while about half were below. The exception was coronary artery disease, for which only about 20 percent of the groups had mean episode costs below the cost of the national mean. Primary cost drivers varied by episode subtype (for example, coronary artery disease with or without myocardial infarction), and depended on whether or not the episode included inpatient hospital stays and post-acute care such as for skilled nursing facilities and rehabilitation facilities. As noted above, risk adjustment was used to account for variations in resource use beyond the medical group's control.

We plan to further develop these episode reports and to include not only additional episodes, but to make this information available to a wider set of medical group practices. Additional clinical conditions under consideration for future QRURs include episode costs related to congestive heart failure, cardiac arrhythmias, hip fracture, osteoarthritis, cataract, glaucoma, chronic obstructive lung disease, and respiratory failure. In addition, we will begin to marry these measures of resource use with clinical quality measures included in the Physician Quality Reporting System, because resource use makes most sense in context of the quality of care furnished.

We have worked with stakeholders and specialty societies to gain input for the next iteration of the CMS Episode Grouper. We received input to examine episode attribution, handling of transfers, relook at risk adjustment, and increased drill down capacity. The CMS Episode Grouper will continue to evolve over the next few years as more experience is gained. More information about the Supplemental QRURs and a summary slide deck of findings on episode costs for medical groups eligible to receive the 2011 supplemental QRURs can be found at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html*.

c. Future Plans for the Physician Feedback Reports

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

The following is a summary of the comments we received about the QRURs. We appreciate commenters' suggestions, but because we did not make any proposals relating to the QRURs, these comments were beyond the scope of the proposed rule. We will consider them as we further implement the Physician Feedback Program.

Comment: We received some comments in response to our description of updates to the QRUR program. Many commenters were very favorable about CMS' work with the physician community to develop the reports and asked that we continue to work with them to refine them. One commenter stated that, ''CMS has taken large strides to improve the clarity and usability of the QRUR reports to present cost and quality information in a meaningful and clear way.'' The commenter also suggested that CMS reconvene the stakeholder workgroup to continue to enhance the feedback reports for 2014 and future years. Some commenters made suggestions about how to improve the reports. One commenter suggested that CMS reduce the length of the report, tailor reports to each specialty by highlighting the measures/conditions of the particular specialist receiving the report, include more details on the physician's patient population, provide recommendations on action items, and accurately identify other providers whose data may have been used in developing the report. Another commenter asked CMS to continue to improve the timeliness and frequency of the reports. One commenter suggested that CMS should report data at the individual NPI level and roll the data up to the TIN level. Some comments suggested that CMS should give providers an opportunity to view their data before they were penalized so that they would have an opportunity to change their behavior. One commenter suggested that CMS should offer providers corrective action plans so that physicians could improve their performance before being impacted by the value based modifier. Some commenters stated that although they realized the statute requires CMS to roll out the value-based modifier to all physicians by January 1, 2017, they were concerned about the aggressive timetable for implementation and noted that providers were being impacted by several programs at once.

Response: We appreciate the commenters' responses to our

description of the QRUR program and their suggestions for how to improve it. We will take these suggestions into consideration as we further implement the Physician Feedback Program.

We also welcome feedback about the recently released reports over the next few months and have several activities scheduled to allow physicians to give us their additional input. In the late summer of 2014, we plan to disseminate the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups of physicians with fewer than 100 eligible professionals will not be subject to the value-based payment modifier in CY 2015. These reports will contain performance on the quality and cost measures used to score the composites and additional information to help physicians coordinate care and improve the quality of care furnished. The reports will be based on the value-based payment modifier policies that we are finalizing in this rule that will take effect January 1, 2014 and that will affect physician payment starting January 1, 2016. Groups of physicians will, therefore, have an opportunity to determine how the policies adopted in this final rule with comment period will apply to them. After the reports are released we will again solicit feedback from physicians and continue to work with our partners to improve them. We note that physicians will have some time to determine the impact of our revised policies and revise their practices accordingly before the new policies impact them. We will study the recommendations submitted in response to this proposed rule and any later suggestions we receive and make plans to implement those that are feasible. We look forward to continue working with the physician community to improve the QRURs.

L. Updating Existing Standards for E-Prescribing Under Medicare Part D

1. Background

a. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Act. Among other things, these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this final rule with comment period and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

(1) Foundation and Final Standards

We utilized several rounds of rulemaking to adopt standards for the e-prescribing program. Its first rule, which was published on November 7, 2005 (70 FR 67568), adopted three standards that were collectively referred to as the ''foundation'' standards. We issued a subsequent rule on April 7, 2008 (73 FR 18918) that adopted additional standards which are referred to as ''final'' standards. One of these standards, the NCPDP Formulary and Benefit Standard, Implementation Guide, Version 1, Release 0 (Version 1.0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) was a subject of the CY 2013 PFS final rule with comment period (77 FR 68892 at 69329) and is the subject of this final rule with comment period. Please see the ''Initial Standards Versus Final Standards'' discussion at 70 FR 67568 in the November 7, 2005 rule for a more detailed discussion about ''foundation'' and ''final'' standards.

(2) Updating e-Prescribing Standards

Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish processes by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in its November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ''updating process'' when a standard could be updated with a newer ''backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**.

(3) The NCPDP Formulary and Benefit Standard in the Part D e-Prescribing Regulations

The backward compatibility concept has been used extensively to update the NCPDP SCRIPT standard in the Part D e-prescribing program, but it has not yet been used to update the adopted NCPDP Formulary and Benefit Standard. We proposed to update the NCPDP Formulary and Benefit 1.0 standard for the first time in the CY 2013 PFS proposed rule (77 FR 44722), but we did not ultimately finalize those proposals. Specifically, we proposed to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits 1.0 effective 60 days from the publication of the final rule, and sought comment on when we should retire NCPDP Formulary and Benefits 1.0 as well as when we should adopt NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard. As was noted in that rule, while recognition of backward compatible versions can be done in an interim final rule in which we waive notice and comment rulemaking, other Part D e-prescribing proposals that were being made at that time required full notice and comment rulemaking, so, as we did not wish to publish two e-prescribing rules contemporaneously, we elected to forgo our usual use of our simplified updating process for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through full notice and comment rulemaking.

2. Proposals

a. Proposed Backward Compatible Standards

As was discussed in the CY 2013 PFS final rule with comment period (77 FR 68892), we were persuaded by

commenters to refrain from retiring Formulary and Benefit Standard 1.0 until NCPDP ceased supporting it on July 1, 2014. As further noted in that rule, we believed it best to delay implementing any of our Formulary and Benefits proposals, including recognitions of NCPDP Formulary and Benefit 3.0 as a backward compatible standard, until closer to that July 1, 2014 date. Our actions at that time were based on a belief that an extended period of use of either 3.0 or 1.0 would be ill-advised.

Having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believed that it was now appropriate to re-propose the recognition of NCPDP Formulary and Benefits 3.0 as a backward compatible version of Formulary and Benefits 1.0 effective 60 days after publication of a final rule until June 30, 2014, and, as discussed below, we also proposed the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard effective July 1, 2014.

Also, as was seen in our prior proposal to recognize backward compatibility using full notice and comment in place of the backward compatible methodology, we also proposed to require users of 3.0 to support users who are still using NCPDP Formulary and Benefit 1.0 until such time as that version is officially retired as a Part D e-prescribing standard and NCPDP Formulary and Benefit 3.0 is adopted as the official Part D e-prescribing standard.

2. Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and Adoption of NCPDP Formulary and Benefit Standard 3.0

As noted in the CY 2013 PFS proposed rule, the NCPDP Formulary and Benefits standard provides a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

Also as noted in that proposed rule, standards are updated over time to take industry feedback and new and modified business needs into account. See the CY 2013 PFS proposed rule (77 FR 45023–45024) for a full discussion of the changes to that were made to the NCPDP Formulary and Benefit 1.0 as it was updated to the NCPDP Formulary and Benefit 3.0.

As noted above, having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believed that it was now appropriate to re-propose the retirement of NCPDP Formulary and Benefits 1.0, effective June 30, 2014, and also proposed the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard, effective July 1, 2014.

To effectuate these proposals, we proposed to revise § 423.160(b)(5). We proposed to place the existing material in a new paragraph (b)(5)(i), which would provide the official formulary and benefit standard for Part D e-prescribing until June 30, 2014. We then proposed to create a second new paragraph ((b)(5)(ii)) to recognize NCPDP Formulary and Benefit 3.0. as a backward compatible version of the official Part D e-prescribing standard (NCPDP Formulary and Benefit 1.0), effective February 10, 2014 through June 30, 2014. Furthermore, we proposed to create a third new paragraph ((b)(5)(iii)) to reflect the retirement of NCPDP Formulary and Benefit 1.0 and the adoption of NCPDP Formulary and Benefit 3.0 as the official Part D e-prescribing standard, effective July 1, 2014. Finally, we proposed to make conforming changes to § 423.160(b)(1). We solicited comment on these proposals.

The following is a summary of the comments we received regarding our proposal to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of the NCPDP Formulary and Benefit Standard 1.0, the proposed retirement of NCPDP Formulary and Benefit Standard 1.0 and the proposed adoption of NCPDP Formulary and Benefit Standard 3.0.

Comment: Commenters generally supported our proposal to adopt the newest version of the NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of the adopted NCPDP Formulary and Benefit 1.0 (60 days after the publication of the final rule), and the retirement of Version 1.0 as an official Part D e-prescribing standard, effective June 30, 2014.

Response: We appreciate the favorable feedback that we received on this proposal and are in agreement with the commenters who responded.

We received a total of 9 comments on our proposal as it related to the effective date of adopting Formulary and Benefit standard 3.0 on July 1, 2014 and the retirement of Formulary and Benefit Standard 1.0 on June, 30 2014 as an official Part D e-prescribing standard.

Comment: Some commenters agreed with our proposal stating that these types of updates are routine and reflect improvements.

Response: We appreciate the feedback we received on the proposed timeline to retire Formulary and Benefit Standard 1.0 on June, 30 2014 and to finalize adoption of the Formulary and Benefit standard 3.0 as the official Part D e-prescribing formulary and benefits standard on July 1, 2014.

Comment: One commenter appreciated our decision in the CY 2013 Medicare Physicians Fee Schedule to delay retiring NCPDP Formulary and benefits Standard 1.0 and adopting the NCPDP Formulary and Benefits 3.0. They are concerned, however, with our proposal to go forward with the proposed effective dates for the adoption of the NCPDP Formulary and Benefits Standard 3.0 and the retirement of Version 1.0 on July 1, 2014. The commenter stated that the current deadline for ICD–10 conversion is October 1, 2014 and many of their resources are devoted to the ICD–10 conversion coding as well as additional systems requirements that they assert they will need to make due to the implementation of the health insurance exchanges on January 1, 2014. They urged CMS to consider delaying the adoption of the NCPDP Formulary and Benefits 3.0 update until early 2015. They stated that this would provide stakeholders with sufficient time to be able to ensure adequate time to address these issues that are coming online in 2014.

Response: We appreciate the comment, but we disagree with the commenter's concerns about the conversion to ICD–10 on October 1, 2014. On October 1, 2014, the ICD–9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD–10 code sets. The transition to ICD–10 is required for everyone subject to the Health Insurance Portability Accountability Act (HIPAA). Industry has had 3 years to prepare for this new requirement and should have already started preparing for the conversion to ICD–10, so we do not believe that the conversion to the NCPDP Formulary and Benefit Standard 3.0 will present an undue added burden.

Furthermore, we do not agree with commenter's assertion that the implementation of the health care exchanges on January 1, 2014 will impose burdens that would affect an entity's ability to implement the NCPDP Formulary and Benefit Standard 3.0 on July 1, 2014.

Furthermore, we would note that the health care exchanges actually went live on October 1, 2013, with coverage for those who enroll beginning as early as January 1, 2014. Any system changes that may be needed will therefore have to have been made by October 1, 2013, or January 1, 2014, depending on what systems the commenter may have been referencing. As such, we do not see how the implementation of the health care exchanges would have any impact on the proposed implementation date for the NCPDP Formulary and Benefit Standard 3.0 on July 1, 2014.

Comment: Two commenters recommended that we delay the proposed June 30, 2014 and July 1, 2014 effective dates 12 months. One commenter stated that 7 months is insufficient time for safe and efficient development and implementation. They asserted that, if the proposed rule goes into effect, the propsed dates would leave EHR developers and EHR users approximately 7 months to do all of the following:

- Complete development to support for the new standard.
- Test the configuration required for the new standard.
- Move this configuration into production.

Another commenter urged CMS to consider an 18-month timeframe between the effective date of this final rule and the compliance date for those subject to the rule. The commenter stated that 18 months would allow EHR developers and healthcare organizations to include the upgrade with other work already in progress for programs such as Meaningful Use and the ICD–10 transition. The commenter recommended the retirement of the use of the current NCPDP Formulary and Benefit 1.0 standard June 30, 2015 and the adoption of NCPDP Formulary and Benefit 3.0 as the official Part D e-prescribing formulary and benefits standard on July 1, 2015.

Another commenter recommended that entities be allowed to use NCPDP Formulary Benefit Version 1.0 or Version 3.0 during a transition period that would end June 30, 2015, and that the NCPDP Formulary and Benefit 3.0 should become the official Part D e-prescribing formulary and benefits standard effective July 1, 2015.

Response: We appreciate the comments but do not believe that there is a compelling reason to allow use of NCPDP Formulary Benefit Version 1.0 or Version 3.0 through June 30, 2015, or to wait to make NCPDP Formulary and Benefit 3.0 the official Part D standard until July 1, 2015. As we have stated in the past, we do not think it is advisable to have extended periods in which either an adopted standard or a backward compatible version of that standard may be used. We believe that allowing the extended use of Version 3.0 as a backward compatible version of Version 1.0 would create confusion.

We understand that our regulations should impose the minimum burden possible on the industry; we therefore re-evaluated our initial timeline proposal in light of recommendations from commenters. We concluded that a July 1, 2014 effective date may be an aggressive timeline for the implementation of the updated NCPDP Formulary and Benefits 3.0 standard, and that some of the commenters have made valid arguments in regards to moving the effective dates back from what we originally proposed.

Commenters have convinced us that if we were to finalize the original timelines as proposed, the industry may not have time to ensure that all of the changes, testing, and implementation activities for the move to Version 3.0 will be completed in time. At the same time, however, we believe that the suggested 18 month delay in effective date is too long. We believe a suitable compromise would be to delay the effective date of our proposals to retire Version 1.0 and to adopt Version 3.0 as the official Part D e-prescribing standard by moving the originally anticipated effective date of this final rule to early 2015. As such, we will retire the Version 1.0 effective February 28, 2015, and adopt Version 3.0 as the official Part D e-prescribing standard effective March 1, 2015. Furthermore, Version 3.0 will be recognized as a backward compatible version of the adopted Version 1.0 from February 10, 2014 through February 28, 2015.

Comment: We received a comment from NCPDP that asked for clarification of our statement in the proposed rule regarding the anticipated date upon which NCPDP would cease supporting NCPDP Formulary and Benefit 1.0. NCPDP stated that they do not intend to cease to support NCPDP Formulary and Benefit Standard Version 1.0, meaning that it will always be included as a a version in the listing of NCPDP publications. They acknowledged that versions may be retired over time as the industry ceases active use of them, but, as in this case, regulations would drive which version would be the appropriate version to be used.

Response: We appreciate the comment from NCPDP clarifying that they will keep NCPDP Formulary and Benefits 1.0 in its list of publications available to its membership.

As a result of the comments, we believe that some of the commenters have made valid arguments in regards to moving the effective dates back from what we originally proposed. We believe a suitable compromise would be to delay the effective date of our proposals to retire Version 1.0 on February 28, 2015 and to adopt Version 3.0 as the official Part D e-prescribing standard on March 1, 2015. This would allow industry adequate time to implement the necessary changes and testing needed to implement. That means that the retirement of Version 1.0 will be effective February 28, 2015, and the adoption of Version 3.0 as the official Part D e-prescribing standard will be effective March 1, 2015.

We are therefore finalizing recognition of the NCPDP Formulary and Benefits Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits Standard 1.0 as of the effective date of this final rule with comment period effective February 10, 2014, the retireent of NCPDP Formulary and Benefits Standard Version 1.0 effective February 28, 2015 and the adoption of NCPDP Formulary and Benefits Standard Version 3.0 as the official Part D e-Prescribing Standard effective March 1, 2015. To effectuate this, we are revising § 423.160(b)(5) to redesignate the current (b)(5) as (b)(5)(i), which will cover prior to February 7, 2014, and adding a new (b)(5)(ii) (which will cover February 10, 2014 until February 28, 2015) and (b)(5)(iii) (which will cover March 1, 2015 and beyond). Section (b)(5)(ii) will be applicable to the period in which Version 3.0. will be recognized as a backward compatible version of Version 1.0, during which time Version 1.0 will remain the official Part D e-prescribing standard. Section 423.160(b)(5)(iii) will be applicable to the period in which Version 3.0 is the official Part D e-prescribing standard.

We will also amend the incorporation by reference in the Part D e-prescribing regulations by adding a reference to the NCPDP Formulary and Benefit Standard 3.0 at § 423.160(c)(1)(vi). Finally, we will make conforming changes to § 423.160(b)(1) to reflect the changes to § 423.160(b)(5).

M. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage for chiropractic services is limited to treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act provided such treatment is legal in the state or jurisdiction where performed. The demonstration expanded Medicare coverage to include: ''(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the state or jurisdiction in which such treatment is provided.'' The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that ''the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented.''

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate BN. In the ''All Neuromusculoskeletal Analysis,'' which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was $114 million higher costs for beneficiaries in areas that participated in the demonstration. In the ''Chiropractic User Analysis,'' which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a $50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the ''Chiropractic User Analysis'' because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services and who may not have become users of chiropractic services even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup $50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping $10 million for each such year through adjustments to the chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

For the CY 2013 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately $470 million, which reflected the statutory 26.5 percent reduction to PFS payments scheduled to take effect that year. The statute was subsequently amended to impose a zero percent PFS update for CY 2013 instead of the 26.5 percent reduction. In large part because of the change in the PFS update, OACT now estimates CY 2013 chiropractic expenditures to be approximately $580 million. Because of the change in projected chiropractic expenditures, we now expect to recoup approximately $11.6 million from the 2 percent payment reduction for chiropractic CPT codes in CY 2013.

We expect to complete the required BN adjustment by recouping the remainder of the chiropractic expenditures in CY 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. While OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: $540 million in 2010; $520 million in 2011; and $580 million in 2012. In total, CMS recouped $32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately $580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately $11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately $44.4 million of the $50 million required for budget neutrality.

In 2014, CMS is reducing the recoupment percentage for the chiropractic codes to ensure the recoupment does not exceed the $50 million required for budget neutrality. OACT estimates chiropractic expenditures in CY 2014 will be approximately $560 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 20 percent reduction to the physician fee schedule conversion factor scheduled to take effect under current law. CMS

plans to recoup the remaining funds, approximately $5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage. We will reflect this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the RVUs. Avoiding an adjustment to the RVUs preserves the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

We received no comments regarding this provision of the PFS. Therefore, as finalized in the CY 2010 PFS regulation and reiterated in the CYs 2011 through 2013 PFS regulations, we are implementing this methodology and recouping excess expenditures under the chiropractic services demonstration from PFS payment for the chiropractor codes as set forth above. This recoupment addresses the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration. We intend for CY 2014 to be the last year of this required recoupment.

N. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Outpatient speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services that are reimbursed by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished in or by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, on January 3, 2013, Congress enacted the American Taxpayer Relief Act of 2012 (ATRA), (Pub. L. 112–240), which will delay payment of these drugs under ESRD PPS until January 1, 2016. In the meantime, such drugs furnished in or by an ESRD facility are not reimbursed as part of a composite rate and thus, are DHS. For purposes of the exception at § 411.355(g), only those drugs that are required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the 2010 PFS final rule (75 FR 73583), we do not believe that any drugs for which there are no injectable equivalents or other forms of administration are required for the efficacy of dialysis. We therefore have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Addendum J of the CY 2013 PFS final rule with comment period.

b. Response to Comments

We received no public comments relating to the Code List that became effective January 1, 2013.

c. Revisions Effective for 2014

The updated, comprehensive Code List effective January 1, 2014, appears as Addendum K in this final rule with comment period and is available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 89 and 90 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2014. Tables 89 and 90 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exceptions in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

We will consider comments regarding the codes listed in Tables 89 and 90. Comments will be considered if we receive them by the date specified in the **DATES** section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS defined in § 411.351.

TABLE 89—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1]/HCPCS CODES

CLINICAL LABORATORY SERVICES	
{No additions}	
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES	
92521	Evaluation of speech fluency
92522	Evaluate speech production
92523	Speech sound lang comprehen
92524	Behavral qualit analys voice
97610	Low frequency non-thermal US
G0460	Autologous PRP for ulcers
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES	
97610	Low frequency non-thermal US
0330T	Tear film img uni/bi w/i&r
0331T	Heart symp image plnr
0332T	Heart symp image plnr spect
0346T+	Ultrasound elastography
A9520	Tc99 Tilmanocept diag 0.5mci
A9586	Florbetapir F18
C9734	U/S trtmt, not leiomyomata
RADIATION THERAPY SERVICES AND SUPPLIES	
C9734	U/S trtmt, not leiomyomata
EPO AND OTHER DIALYSIS-RELATED DRUGS	
{No additions}	
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES	
90661	Flu vacc cell cult prsv free
90673	Flu vacc RIV3 no preserv
90685	Flu vac no prsv 4 val 6-35 m
90686	Flu vac no prsv 4 val 3 yrs+
90688	Flu vacc 4 val 3 yrs plus im

[1] CPT codes and descriptions only are copyright 2013 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 90—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1]/HCPCS CODES

CLINICAL LABORATORY SERVICES	
{No deletions}	
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES	
0183T	Wound Ultrasound
92506	Speech/hearing evaluation
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES	
{No deletions}	
RADIATION THERAPY SERVICES AND SUPPLIES	
{No deletions}	
EPO AND OTHER DIALYSIS-RELATED DRUGS	
{No deletions}	
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES	
{No deletions}	

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2014 PFS proposed rule (78 FR 43506), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). No comments were received.

A. ICRs Regarding Medical Services Coverage Decisions That Relate to Health Care Technology (§ 405.211)

Over the past 18 years, there have been approximately 4000 IDE studies approved that are potentially coverable by Medicare, averaging to about 222 per year. If the sponsor requests a second review, the documents will have to be sent again. We estimate that this may happen 5–8 percent of the time. Adding another 8 percent brings the total estimate to approximately 240 requests per year.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The salary estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the May 2013 Employer Costs for Employee Compensation report by the Bureau. The burden associated with the requirements under § 405.211 is the time and effort it will take a study sponsor that is seeking Medicare coverage related to an FDA-approved Category A or B IDE to prepare the request and supporting documents (a copy of each of the following: FDA approval letter of the IDE, IDE study protocol, IRB approval letter, NCT number, and supporting materials (as needed).

For the most part, the documents are copies of communications between the study sponsor and the FDA. Accordingly, we estimate that it will take 1 to 2 hours for an executive administrative assistant in a medical device company to prepare the required information. We estimate that for 240 requests per year, that the total time to be expended by all potential study sponsors is estimated to be between 240 to 480 hours. In deriving costs to the public, we used the Bureau of Labor Statistics May 2012 estimate of $24.14 + 35% in fringe benefits for estimated hourly wage of $32.59 for an executive administrative assistant (occupation code 43–6011). We estimate the cost to be between $7.822–$15,643 per study, for 222 potential IDE study sponsors plus a potential 19 additional submissions. If the average time of a study is 2 years, the annualized cost is $3,911–$15,643 years applications or $16.30–$39.59 per study.

The higher figure is used for the burden calculation in our PRA submission to OMB. The preceding requirements and burden estimates will be submitted to OMB under OCN 0938-New (CMS–10511).

B. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

We are making certain revisions to § 414.90, primarily to include our final policies for the qualified clinical data registry option. Please note that we solicited but received no specific public comment either supporting or opposing the impact statements related to our proposals for the PQRS. Therefore, our estimates below are based on the final requirements for participation in the PQRS in 2014.

We are revising § 414.90(b), (c), and (e) and adding new paragraphs (h) and (j) of § 414.90 to indicate our requirements for the qualified clinical data registry option, including specifying the criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive and 2016 PQRS payment adjustment. In addition, we are revising § 414.90(g) and newly redesignated § 414.90(i) to indicate the addition of a new PQRS reporting mechanism for group practices—the CMS-certified survey vendor—as well as to specify the satisfactory reporting criteria for the 2014 PQRS incentive and 2016 PQRS payment adjustment. While the sections contain information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule does not revise any of the information collection requirements or burden estimates that are associated with those provisions.

The preamble of this final rule with comment period discusses the background of the PQRS, provides information about the measures and reporting mechanisms that are available to eligible professionals and group practices who choose to participate in 2014, and provides the criteria for satisfactory reporting data on quality measures in 2014 (for the 2014 PQRS incentive and the 2016 PQRS payment adjustment). Below are our burden estimates for participating in the PQRS in 2014 which are subject to OMB review/approval under OCN 0938–1059. (CMS–10276).

1. Participation in the 2014 PQRS

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are adding and modifying certain requirements for the 2014 PQRS, this section modifies the impact statement provided in the CY 2013 PFS final rule with comment period for reporting in 2014. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter ''the PQRS Reporting Experience''). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/*. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27 percent of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS will rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 remains accurate.

With respect to the estimated amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent

incentive (that is, a bonus payment equal to 0.5 percent of the total allowed part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27 percent of 1 million eligible professionals) 270,000 eligible professionals. At $1,059 per eligible professional, the PQRS will distribute approximately $286 million in incentive payments for 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- For an eligible professional or group practice using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice will attempt to report quality measures data with the intention of earning the 2014 PQRS incentive and not simply to avoid the 2016 PQRS payment adjustment. Therefore, an eligible professional or group practice will report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

Please note that these estimates do not reflect total costs estimates for participating in PQRS, but rather the adjustments (+/−) associated with the changes for 2014.

2. Burden Estimate on Participation in the 2014 PQRS—New Individual Eligible Professionals: Preparation

For an eligible professional who wishes to participate in PQRS as an individual, the eligible professional need not indicate his/her intent to participate. Instead, the eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice will spend 5 hours—which includes 2 hours to review PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in PQRS will be approximately $80 ($16/hour × 5 hours).

3. Burden Estimate on Participation in the 2014 PQRS via the Claims-based Reporting Mechanism—Individual Eligible Professionals

Historically, the claims-based reporting mechanism is the most widely used reporting mechanism in PQRS. In 2011, 229,282 of the 320,422 eligible professionals (or 72 percent of eligible professionals) used the claims-based reporting mechanism. In the CY 2013 PFS final rule with comment period, we estimated that approximately 320,000 eligible professionals, whether participating individually or in a group practice, will participate in PQRS by CY 2014 (77 FR 69338). We believe this estimate should be further modified to reflect a lower participation estimate in 2014 for the following reasons:

- We are eliminating the option to report measures groups via claims for the 2014 PQRS incentive and 2016 PQRS payment adjustment.
- We are increasing the number of measures that an eligible professional must report to meet the criteria for satisfactory reporting for the 2014 PQRS incentive from 3 measures to 9, but lower the reporting threshold to 50 percent.
- We are removing the claims-based reporting mechanism as an option for reporting certain individual quality measures.

We estimate that approximately 230,000 eligible professionals (that is, the same number of eligible professionals who participated in the PQRS using the claims-based reporting mechanism in 2011) will participate in the PQRS using the claims-based reporting mechanism. Therefore, we estimate that approximately 58 percent of the eligible professionals participating in PQRS will use the claims-based reporting mechanism.

With respect to an eligible professional who participated in PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submitted for payment. PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims ranges from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures ranges from 2.25 minutes to 108 minutes. Using an average labor cost of $40/hour, we estimated that the time cost of reporting for an eligible professional via claims ranges from $1.50 (2.25 minutes or 0.0375 hours × $40/hour) to $72.00 (108 minutes or 1.8 hours × $40/hour) per reported case. With respect to how many cases an eligible professional will report when using the claims-based reporting mechanism, we established that an eligible professional needs to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional reports varies depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent for claims-based reporting, we found that the median number of reporting cases for each measure was 9. Since we reduced the reporting threshold to 50 percent, we estimate that the average number of reporting cases for each measure will be reduced to 6. Based on these estimates, we estimate that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism ranges from ($1.50/per reported case × 6 reported cases) $9.00 to ($72.00/reported case × 6 reported cases) $432.

4. Burden Estimate on PQRS Participation in CY 2014 via the Qualified Registry, Qualified Clinical Data Registry, or EHR Reporting Mechanisms

We noted previously that we estimated a significant reduction in the number of eligible professionals using the claims-based reporting mechanism to report PQRS quality measures data in 2014. Specifically, we estimated that approximately 230,000 eligible professionals would participate in the PQRS using the claims-based reporting

mechanism in 2014. Therefore, we estimated that the remainder of the eligible professionals (170,000) would participate in PQRS using either the qualified registry, qualified clinical data registry, EHR (using either a direct EHR or EHR data submission vendor), or the GPRO web interface reporting mechanisms.

With respect to participation in a qualified registry or qualified clinical data registry, we are combining our estimates for the number of eligible professionals we believe will use the qualified registry and qualified clinical data registry reporting mechanisms for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We are combining these estimates because we believe that, at least for this initial year, many of the registries that become qualified clinical data registries will also be existing qualified registries. As such, we anticipate there will be little to no additional, new registries that will submit quality measures data on behalf of eligible professionals to the PQRS for purposes of the 2014 PQRS incentive and 2016 PQRS payment adjustment.

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using a qualified registry or qualified clinical data registry would remain the same, given that eligible professionals use registries for functions other than PQRS and therefore, would not obtain a qualified registry or qualified clinical data registry solely for PQRS reporting in CY 2014. Please note that this estimate would include participants choosing the new qualified clinical data registry reporting mechanism. At least in its initial stage, we believe most of the vendors that would be approved to be a qualified clinical data registry would be existing qualified registries.

In 2011, 560 (or less than 1 percent) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals and group practices will transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 50,000 eligible professionals (which is the same estimate as we are providing for eligible professionals who use the qualified registry or qualified clinical data registry-based reporting mechanisms), whether participating as an individual or part of a group practice, will use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participated in PQRS via a qualified registry, qualified clinical data registry, direct EHR product, or EHR data submission vendor's product, we believe there will be little to no burden associated for an eligible professional to report quality measures data to CMS, because the eligible professional will select a reporting mechanism to submit the quality measures data on the eligible professional's behalf. Therefore, the actual reporting is performed by the reporting mechanism, not the eligible professional.

While we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice will not use a qualified registry, qualified clinical data registry, or EHR data submission vendor product, or purchase a direct EHR product, solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of using a qualified registry, qualified clinical data registry, or EHR data submission vendor product, or purchasing a direct EHR product in our burden estimates.

5. Burden Estimate on PQRS Participation in CY 2014—Group Practices

Please note that with the exception of the estimates associated with a group self-nominating to participate in the PQRS under the group practice reporting option (GPRO), this section only contains our estimates for group practices who participate in the PQRS under the GPRO via the GPRO web interface reporting mechanism. We note that the burden associated with reporting quality measures for group practices using the qualified registry or EHR-based reporting mechanisms are included in the estimates we provided for the qualified registry or EHR-based reporting mechanisms above. According to the 2011 PQRS and eRx Experience report, of the 101 practices participating in the GPRO, 54 of these practices participated using the GPRO web interface (formerly referred to as ''the GPRO tool''). We estimate that because are applying the value-based payment modifier to all group practices of 10 or more eligible professionals, we estimate that approximately 30 percent of such group practices, or about 5,100 group practices, will participate in the PQRS under the GPRO for purposes of the 2014 PQRS incentive and the 2016 payment adjustment. In addition, we estimate that of the 5,100 group practices that are expected to self-nominate to participate in the PQRS under the GPRO, approximately 70,000 eligible professionals (that is, the remainder of the eligible professionals not participating in PQRS using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms), representing about 30 percent of the groups with 100 or more eligible professionals (or about 340 groups), will choose to participate in PQRS using the GPRO web interface for purposes of the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

Unlike eligible professionals who choose to report individually, eligible professionals choosing to participate as part of a group practice under the GPRO will need to indicate their intent to participate in PQRS as a group practice. The total burden for group practices who submit PQRS quality measures data via the GPRO web-interface will be the time and effort associated with submitting this data. To submit quality measures data for PQRS, a group practice needs to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in PQRS as a group practice, we believe it takes approximately 6 hours—including 2 hours to decide to participate in PQRS as a group practice; 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process is ($16/hour × 6 hours) $96.

With respect to reporting PQRS quality measures using the GPRO web-interface, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface is approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS

quality measures data for an applicable year is ($40/hour × 79 hours) $3,160.

In addition to the GPRO web interface, please note that we are finalizing a new reporting mechanism that is available to group practices comprised of 25+ eligible professionals: The certified survey vendor for CG–CAHPS measures. With respect to using a certified survey vendor, we believe there is little to no burden associated for a group practice to report the CG CAHPS survey data to CMS because the certified survey vendor will report the CG CAHPS survey questions on the group practice's behalf. Although there may be start-up costs associated with using a certified survey vendor, we believe that a group practice will not use a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of using a certified survey vendor in our burden estimates.

6. Burden Estimate on PQRS Vendor Participation in CY 2014

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that entities that wish to become qualified clinical data registries will incur costs associated with participating in PQRS. However, we believe that the burden associated with participating in PQRS for these entities is very similar to the burden associated with existing qualified registries participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimated that approximately 50 registries will self-nominate to be considered a qualified registry for PQRS. With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries and qualified clinical data registries that submit quality measures data will be the time and effort associated with submitting this data. To submit quality measures data for the 2014 PQRS reporting periods, a registry needs to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimate that it takes a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wished to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report quality measures data under the PQRS. Therefore, we estimate that it costs a registry approximately ($16.00/hour × 10 hours) $160 to become qualified to submit quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, the burden associated with reporting is the time and effort associated with the registry and qualified clinical data registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. In addition to submitting numerator and denominator data on quality measures and calculating these measure results, qualified clinical data registries are required to perform additional functions, such as providing feedback to its eligible professionals at least 4 times a year and establishing a method to benchmark and, where appropriate, risk adjust its quality measure results. We believe, however, that registries and qualified clinical data registries already perform these functions for their eligible professionals irrespective of participating in PQRS. Therefore, we believe there is little to no additional burden associated with reporting quality measures data. Whether there is any additional reporting burden varies with each registry, depending on the registry's level of savvy with submitting quality measures data for PQRS.

For CY 2014, we are finalizing a new PQRS option that includes a new reporting mechanism—the qualified clinical data registry. In this final rule with comment period, we set forth the requirements for a vendor to become qualified to become a qualified clinical data registry. Under the final requirements, we note that a vendor can be both a traditional qualified registry and qualified clinical data registry under the PQRS. Indeed, as we noted previously, we believe that many of the entities that will seek to become qualified clinical data registries will be similar to the existing qualified registries. In addition, the process that we are adopting for becoming a qualified clinical data registry is similar to the process for becoming a qualified registry. Therefore, we do not believe this new reporting mechanism will impact our registry estimates.

7. Summary of Burden Estimates on Participation in the 2014 PQRS—Eligible Professionals and Vendors

TABLE 91—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA FOR ELIGIBLE PROFESSIONALS

	Hours	Cases	Number of measures	Hourly rate	Cost per respondent	Number of respondents	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80	320,422	$32,000,000
Individual EP: Claims	0.2	6	3	40	144	230,000	33,120,000
Individual EP: Registry	N/A	1	N/A	N/A	Minimal	40,422	[1] N/A
Individual EP: EHR	N/A	1	N/A	N/A	Minimal	50,000	[1] N/A
Group Practice: Self-Nomination	6.0	1	N/A	16	96	5,100	489,600
Group Practice: Reporting	79	1	N/A	40	3,160	340	1,074,400

[1] We believe that eligible professionals who choose to report quality measures data to PQRS using a registry, a qualified clinical data registry, an EHR, or an EHR data submission vendor are already submitting quality measures data for other purposes. Therefore, there is little to no burden associated with reporting the quality data to CMS under PQRS.

TABLE 92—ESTIMATED COSTS TO REGISTRIES TO PARTICIPATE IN PQRS

	Hours	Hourly rate	Cost	Number of respondents	Total cost
Registry: Self-Nomination	10	$16	$160	50	$8,000

C. The Medicare EHR Incentive Program

The Medicare EHR Incentive Program provides incentive payments to eligible professionals, eligible hospitals, and CAHs that demonstrate meaningful use of certified EHR technology. We believe any burden or impact associated with this rule's changes to the EHR Incentive Program are already absorbed by OCN 0938–1158 and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

D. Submission of PRA-Related Comments

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS–1600–FC]

Fax: (202) 395–6974; or

Email: OIRA_submission@omb.eop.gov.

PRA-specifc comments must be received on/by January 9, 2014.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We considered all comments we received by the date and time specified in the **DATES** section of this preamble, and, when we proceeded with a subsequent document, we responded to the comments in the preamble to that document.

VI. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. We assign interim RVUs to any new codes based on a review of the AMA RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific AMA RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received AMA RUC recommendations for only one component (work or PE) but not both. By reviewing these AMA RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject other payment policies. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes until notice and comment procedures could be completed.

For the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

Section II.E. of this final rule with comment period discusses our review and decisions regarding the AMA RUC recommendations. Similar to the AMA RUC recommendations for new and revised codes previously discussed, due to the timing of the AMA RUC recommendations for the services identified as potentially misvalued codes, it is impracticable for CMS to provide for notice and comment regarding specific revisions prior to publication of this final rule with comment period. We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and re-evaluated by the AMA RUC, on an interim final basis for CY 2013. The revisions of RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources associated with furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate a distortion in the payment for other services under the PFS. Implementing the changes on an interim basis allows for a more equitable distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to the AMA RUC's recommendation to CMS. For the reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis.

We are providing a 60-day public comment period.

In the absence of an appropriation for CY 2014 or a Continuing Resolution, there was a lapse in funding, which lasted from October 1 through October 16, 2013, when only excepted operations continued. This largely excluded work on this final rule with comment period. Accordingly, most of the work on this final rule with comment period was not completed in accordance with our usual schedule for final CY payment rules, which aims for an issuance date of November 1 followed by an effective date of January 1 to ensure that the policies are effective at the start of the calendar year to which they apply.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. We believe it would be contrary to the public interest to delay the effective date of the MPFS portions of this final rule with comment period. In accordance with section 1848(b)(1) of the statute, the MPFS is a calendar-year payment system. We typically issue the final rule by November 1 of each year to comply with section 1848(b)(1) of the statute and to ensure that the payment policies for the system are effective on January 1, the first day of the calendar year to which the policies are intended to apply. If the effective date of this final rule with comment period is delayed by 60 days, the MPFS for CY 2014 adopted in this final rule with comment period will not be effective as of the beginning of the payment year. Section 1848(d) of the Act requires application of an update, calculated using the SGR methodology, to the CF that is used to calculate payments under the MPFS. The statutory update is required to be applied to the CF for the previous year in order to calculate the CF for the succeeding year. As such, it is necessary that the statutory update to the CF take effect as of the beginning of the calendar year in order to adjust MPFS payments as prescribed by statute. In addition, in this final rule with comment period, we review and revise values for specific services, and adopt or revise other policies that relate to the MPFS for CY 2014 or future years. Section 1848(c)(2)(B)(ii)(II) of the Act requires that adjustments to relative values under the MPFS be made in a budget neutral manner. We believe that, in order to preserve budget neutrality as required by statute and to promote an orderly transition to a new payment year, it is in the public interest for all of these MPFS policies to take effect in conjunction with the statutory update to the CF for CY 2014, and we find that it would be contrary to the public interest to do otherwise. We are finalizing the MPFS in this CY 2014 final rule with comment period and, in order to adhere to the statutory requirements that an adjusted CF apply to services furnished on or after January 1, 2014, and that budget neutrality be maintained, this final rule must be effective on that date.

Additionally, we believe it would be contrary to the public interest to delay the effective date of the PQRS, value-based payment modifier, EHR incentive program, and Medicare Shared Savings provisions of this final rule with comment period. PQRS incentives for 2014 and PQRS payment adjustments for 2016, as authorized under subsections (m) and (a) of section 1848, will be based, in part, on the policies finalized in this final rule, including the requirements for reporting quality data beginning January 1, 2014. The CY 2016 value-based payment modifier, as authorized under section 1848(p), will be determined according to final policies adopted in this rule and using a performance period that begins on January 1, 2014. We are also finalizing policies in this rule that pertain to the reporting of clinical quality measures for the EHR Incentive Program during CY 2014, which will be used to determine incentive payments and payments adjustments under sections 1848(o) and (a)(7), respectively. If the effective date of this final rule with comment period is delayed by 60 days, the PQRS policies adopted in this final rule will not be effective until after January 1, 2014. This would be contrary to the public's interest in ensuring that eligible professionals have the full benefit of reporting during CY 2014, receive appropriate incentive payments in a timely manner, and that their physician fee schedule payments in 2016 are properly adjusted to reflect their reporting on quality measure data in 2014. For the same reasons, we believe it would be contrary to the public interest to delay by 60 days the effective date of the policies related to the CY 2016 value-based payment modifier and the EHR Incentive Program. In addition, under the authority provided by section 1899(b)(3)(D) of the Act, certain PQRS requirements regarding reporting for purposes of incentive payments and the payment adjustment under section 1848(a)(8) were incorporated in the Medicare Shared Savings Program. Accordingly, for the same reasons described above, it would also be contrary to the public interest to delay the effective date of the provisions regarding PQRS reporting under the Medicare Shared Savings Program beyond January 1, 2014.

Therefore, we find good cause to waive the 60-day delay in the effective date for this final rule with comment period as explained above. We note that our waiver of the delayed effective date only applies to the provisions noted above that are being adopted in this final rule with comment period. The delayed effective date is not waived for other provisions of this final rule with comment period, and those policies will be effective on January 27, 2014.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Affordable Care Act (Pub. L. 111–148), the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), the American Taxpayer Relief Act (ATRA) of 2013 (Pub. L. 112–240), and other statutory changes. This final rule with comment period also is necessary to make changes to other Part B related policies.

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this

section, that the PFS provisions included in this final rule with comment period will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million in any 1 year (for details see the SBA's Web site at *http://www.sba.gov/content/small-business-size-standards#* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

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

For purposes of the RFA, physicians, NPPs, and suppliers are considered small businesses if they generate revenues of $10 million or less based on SBA size standards. Approximately 95 percent of providers and suppliers are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this final rule with comment period is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This final rule with comment period will impose no mandates on state, local, or tribal governments or on the private sector.

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

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

C. Relative Value Unit (RVU) Impacts

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

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

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2013 with payment rates for CY 2014 using CY 2012 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

We note that these impacts do not include the effect of the January 2014 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or ''target'' expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the ''SGR'' methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with sections 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress.

Although the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. We provide our most recent estimate of the SGR and physician update for CY 2014 in section II.G. of this final rule with comment period.

Table 93 shows the payment impact by Medicare specialty. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different from those shown in Table 93 (CY 2014 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty).

The following is an explanation of the information represented in Table 93:

- *Column A (Specialty):* The Medicare specialty code as reflected in our physician/supplier enrollment files.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work and Malpractice (MP) RVU Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to new, revised, and misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2014 impact on total allowed charges of the changes in the PE RVUs, including the impact of changes due to new, revised, and misvalued codes, the statutory change to the equipment utilization rate from 75 percent to 90 percent for expensive diagnostic imaging equipment, the implementation of the ultrasound recommendation to replace expensive ultrasound rooms with less expense portable ultrasound units, and other miscellaneous and minor provisions.
- *Column E (Impact of Adjusting the RVUs to Match the Revised MEI Weights):* This column shows the estimated CY 2014 combined impact on total allowed charges of the changes in the RVUs and conversion factor adjustment resulting from adjusting the RVUs to match the revised MEI weights.
- *Column F (Cumulative Impact):* This column shows the estimated CY 2014 combined impact on total allowed charges of all the changes in the previous columns.

TABLE 93—CY 2014 PFS FINAL RULE WITH COMMENT PERIOD ESTIMATED IMPACT TABLE: IMPACTS OF WORK, PRACTICE EXPENSE, AND MALPRACTICE RVUS, AND THE MEI ADJUSTMENT *

Specialty	Allowed charges (mil)	Impact of RVU changes		Impact of adjusting the RVUs to match the revised MEI weights	Combined impact
		Impact of work and MP RVU changes	Impact of PE RVU changes		
(A)	(B)	(C)	(D)	(E)	(F)
Total	$87,552	0	0	0	0
01—ALLERGY/IMMUNOLOGY	214	0	0	−3	−3
02—ANESTHESIOLOGY	1,871	0	0	1	1
03—CARDIAC SURGERY	357	0	0	2	2
04—CARDIOLOGY	6,461	0	2	−1	1
05—COLON AND RECTAL SURGERY	159	0	0	0	0
06—CRITICAL CARE	276	0	0	2	2
07—DERMATOLOGY	3,123	−1	1	−2	−2
08—EMERGENCY MEDICINE	2,946	0	0	2	2
09—ENDOCRINOLOGY	449	0	0	0	0
10—FAMILY PRACTICE	6,402	0	0	0	0
11—GASTROENTEROLOGY	1,909	−1	−1	0	−2
12—GENERAL PRACTICE	536	0	0	0	0
13—GENERAL SURGERY	2,254	0	0	0	0
14—GERIATRICS	235	0	0	1	1
15—HAND SURGERY	151	0	0	−1	−1
16—HEMATOLOGY/ONCOLOGY	1,896	0	0	−2	−2
17—INFECTIOUS DISEASE	639	0	0	2	2
18—INTERNAL MEDICINE	11,503	0	0	1	1
19—INTERVENTIONAL PAIN MGMT	644	−1	−2	−1	−4
20—INTERVENTIONAL RADIOLOGY	221	−1	0	−1	−2
21—MULTISPECIALTY CLINIC/OTHER PHY	80	0	−1	1	0
22—NEPHROLOGY	2,134	0	0	1	1
23—NEUROLOGY	1,509	0	−1	0	−1
24—NEUROSURGERY	718	0	0	0	0
25—NUCLEAR MEDICINE	51	0	0	0	0
27—OBSTETRICS/GYNECOLOGY	693	0	2	−1	1
28—OPHTHALMOLOGY	5,609	0	0	0	0
29—ORTHOPEDIC SURGERY	3,702	−1	−1	0	−2
30—OTOLARNGOLOGY	1,133	0	−1	−1	−2
31—PATHOLOGY	1,141	−4	−2	0	−6
32—PEDIATRICS	64	0	0	0	0
33—PHYSICAL MEDICINE	1,007	0	−1	0	−1
34—PLASTIC SURGERY	372	0	0	0	0
35—PSYCHIATRY	1,181	4	1	1	6

TABLE 93—CY 2014 PFS FINAL RULE WITH COMMENT PERIOD ESTIMATED IMPACT TABLE: IMPACTS OF WORK, PRACTICE EXPENSE, AND MALPRACTICE RVUS, AND THE MEI ADJUSTMENT *—Continued

Specialty	Allowed charges (mil)	Impact of RVU changes		Impact of adjusting the RVUs to match the revised MEI weights	Combined impact
		Impact of work and MP RVU changes	Impact of PE RVU changes		
(A)	(B)	(C)	(D)	(E)	(F)
36—PULMONARY DISEASE	1,783	0	0	1	1
37—RADIATION ONCOLOGY	1,788	0	3	−2	1
38—RADIOLOGY	4,655	0	−2	0	−2
39—RHEUMATOLOGY	553	0	−2	−2	−4
40—THORACIC SURGERY	335	0	0	1	1
41—UROLOGY	1,864	0	−1	0	−1
42—VASCULAR SURGERY	931	0	−1	−1	−2
43—AUDIOLOGIST	57	0	1	−1	0
44—CHIROPRACTOR	729	5	6	1	12
45—CLINICAL PSYCHOLOGIST	587	6	−1	3	8
46—CLINICAL SOCIAL WORKER	414	6	−2	4	8
47—DIAGNOSTIC TESTING FACILITY	790	0	−6	−5	−11
48—INDEPENDENT LABORATORY	818	−2	0	−3	−5
49—NURSE ANES/ANES ASST	1,061	0	0	3	3
50—NURSE PRACTITIONER	1,954	0	0	1	1
51—OPTOMETRY	1,116	0	0	−1	−1
52—ORAL/MAXILLOFACIAL SURGERY	45	0	1	−2	−1
53—PHYSICAL/OCCUPATIONAL THERAPY	2,818	0	1	−1	0
54—PHYSICIAN ASSISTANT	1,414	0	0	0	0
55—PODIATRY	1,998	0	0	−1	−1
56—PORTABLE X—RAY SUPPLIER	113	0	2	−4	−2
57—RADIATION THERAPY CENTERS	63	0	5	−6	−1
98—OTHER	25	0	0	1	1

*Table 93 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the January 2014 conversion factor change required under current law.

2. CY 2014 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the following major factors. The first factor is our rescaling of the RVUs to match the weights assigned to work, PE and MP in the revised MEI, as discussed in section II.B. of this final rule with comment period. A conversion factor (CF) adjustment is also made to assure budget neutrality for this adjustment in RVUs. The second factor involves service-level changes to RVUs for new, revised, and misvalued services. In addition, a number of other changes contribute to the impacts shown in Table 93. Other factors include a statutory change that requires us to use a 90 percent equipment utilization rate rather than the previously used 75 percent for expensive diagnostic imaging equipment as discussed in section II.A.2.f. of this final rule with comment period, updates to direct practice expense inputs for ultrasound services, as discussed in section II.A.5. of this final rule with comment period and adjustments to time for some services, as discussed in section II.B.3.c. of this final rule with comment period.

b. Combined Impact

Column F of Table 93 displays the estimated CY 2014 combined impact on total allowed charges by specialty of all the RVU changes. These impacts range from an increase of 12 percent for chiropractors to a decrease of 10 percent for diagnostic testing facilities. Again, these impacts are estimated prior to the application of the negative CY 2014 CF update applicable under the Act.

Table 94 (Impact of Final rule with comment period on CY 2014 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included CY 2014 payment rates with and without the effect of the CY 2014 negative PFS CF update for comparison purposes. We selected these procedures from among the most commonly furnished by a broad spectrum of physician specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this final rule with comment period.

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TABLE 94: Impact of Final Rule with Comment Period on CY 2014 Payment for Selected Procedures*

			Facility					Non-Facility				
CPT/ HCPCS [1]	MOD	Short Descriptor	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)
11721		Debride nail 6 or more	$24.50	$25.30	3%	$18.59	-24%	$44.91	$44.89	0%	$33.00	-27%
17000		Destruct premalg lesion	$57.16	$53.09	-7%	$39.02	-32%	$83.36	$74.82	-10%	$54.99	-34%
27130		Total hip arthroplasty	$1,454.48	$1,393.78	-4%	$1,024.43	-30%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,242.18	$1,260.53	1%	$926.49	-25%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,552.81	$1,393.06	-10%	$1,023.91	-34%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,906.31	$1,958.13	3%	$1,439.23	-25%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,096.22	$1,201.38	10%	$883.02	-19%	NA	NA	NA	NA	NA
43239		Egd biopsy single/multiple	$174.54	$152.13	-13%	$111.82	-36%	$359.28	$404.02	12%	$296.96	-17%
66821		After cataract laser surgery	$325.26	$323.50	-1%	$237.78	-27%	$344.99	$341.32	-1%	$250.87	-27%
66984		Cataract surg w/iol 1 stage	$667.87	$671.59	1%	$493.62	-26%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$520.55	$521.95	0%	$383.64	-26%	$538.92	$539.41	0%	$396.47	-26%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	$23.82	$23.87	0%	$17.55	-26%
71010	26	Chest x-ray 1 view frontal	$8.85	$9.26	5%	$6.81	-23%	$8.85	$9.26	5%	$6.81	-23%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$114.66	$115.44	1%	$84.85	-26%
77056	26	Mammogram both breasts	$42.19	$44.18	5%	$32.47	-23%	$42.19	$44.18	5%	$32.47	-23%
77057		Mammogram screening	NA	NA	NA	NA	NA	$81.66	$82.30	1%	$60.49	-26%
77057	26	Mammogram screening	$34.02	$35.63	5%	$26.19	-23%	$34.02	$35.63	5%	$26.19	-23%
77427		Radiation tx management	$178.28	$185.62	4%	$136.43	-23%	$178.28	$185.62	4%	$136.43	-23%
88305	26	Tissue exam by pathologist	$36.74	$38.12	4%	$28.02	-24%	$36.74	$38.12	4%	$28.02	-24%
90935		Hemodialysis one	$71.11	$73.04	3%	$53.68	-25%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	$53.08	$54.51	3%	$40.07	-25%	$87.44	$86.58	-1%	$63.63	-27%
92014		Eye exam&tx estab pt	$80.29	$82.30	2%	$60.49	-25%	$126.23	$125.41	-1%	$92.18	-27%
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	$18.37	$16.75	-9%	$12.31	-33%
93010		Electrocardiogram report	$8.17	$8.55	5%	$6.28	-23%	$8.17	$8.55	5%	$6.28	-23%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$79.61	$75.53	-5%	$55.52	-30%

			Facility					Non-Facility				
CPT/ HCPCS [1]	MOD	Short Descriptor	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)	CY 2013 [2]	CY 2014 [3] (pre update)	% Change (pre update)	CY 2014 [4] (post update)	% Change (post update)
93307	26	Tte w/o doppler complete	$44.23	$45.60	3%	$33.52	-24%	$44.23	$45.60	3%	$33.52	-24%
93458	26	L hrt artery/ventricle angio	$315.73	$326.00	3%	$239.61	-24%	$315.73	$326.00	3%	$239.61	-24%
98941		Chiropract manj 3-4 regions	$30.62	$35.27	15%	$25.92	-15%	$36.40	$41.33	14%	$30.38	-17%
99203		Office/outpatient visit new	$75.19	$76.96	2%	$56.56	-25%	$108.19	$107.95	0%	$79.35	-27%
99213		Office/outpatient visit est	$49.67	$51.30	3%	$37.71	-24%	$72.81	$72.68	0%	$53.42	-27%
99214		Office/outpatient visit est	$76.55	$78.74	3%	$57.87	-24%	$106.83	$107.24	0%	$78.82	-26%
99222		Initial hospital care	$134.73	$138.24	3%	$101.60	-25%	NA	NA	NA	NA	NA
99223		Initial hospital care	$198.01	$203.44	3%	$149.53	-24%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$38.11	$39.19	3%	$28.81	-24%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$70.09	$71.97	3%	$52.90	-25%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$101.05	$104.03	3%	$76.47	-24%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$212.30	$218.40	3%	$160.53	-24%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$104.79	$106.88	2%	$78.56	-25%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$59.88	$61.64	3%	$45.30	-24%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$114.66	$117.93	3%	$86.68	-24%	NA	NA	NA	NA	NA
99291		Critical care first hour	$217.75	$223.75	3%	$164.45	-24%	$272.18	$273.62	1%	$201.11	-26%
99292		Critical care addl 30 min	$109.55	$112.23	2%	$82.49	-25%	$120.78	$122.92	2%	$90.34	-25%
99348		Home visit est patient	NA	NA	NA	NA	NA	$82.34	$84.08	2%	$61.80	-25%
99350		Home visit est patient	NA	NA	NA	NA	NA	$173.52	$177.78	2%	$130.67	-25%
G000		Immunization admin	NA	NA	NA	NA	NA	$25.86	$24.94	-4%	$18.33	-29%

[1] CPT codes and descriptions are copyright 2013 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
[2] Payments based on the 2013 conversion factor of 34.0230.
[3] Payments based on the 2013 conversion factor of 34.0230, adjusted to 35.6446 to include the budget neutrality adjustment.
[4] Payments based on the estimated 2014 conversion factor of 27.2006.

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D. Effect of Changes to Medicare Telehealth Services Under the PFS

As discussed in section II.E.3. of this final rule with comment period, we are finalizing our policy to refine our definition of rural as it applies to HPSAs eligible for telehealth services as well as add transitional care management services to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of current Medicare telehealth services, including services similar to transitional care management, we estimate no significant impact on PFS expenditures from the additions.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements we are updating the GPCIs for each Medicare payment locality. The GPCIs incorporate the use of updated data and cost share weights as discussed in II.E. The Act requires that updated GPCIs be phased in over 2 years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2014) and the fully implemented year (CY 2015). The GAFs reflect the use of the updated underlying GPCI data, and the revised cost share weights. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. Although we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual geographic adjustment to payment for any actual service will be different from the GAF to the extent that the proportions of work, PE and malpractice expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 22 payment localities where the fully implemented (CY 2015) GAF moves up by more than 1 percent (11 payment localities) or down by more than 2 percent (11 payment localities). The impacts on the GPCIs are primarily attributed to the expiration of the 1.000 work GPCI floor. The use of updated underlying GPCI data and cost share weights has a minimal impact on locality GAFs. The total impact of the GPCI revisions is shown in the 2015 GPCI values of Addendum E.

We note that the CY 2014 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in Addenda D and E reflect the elimination of the 1.0 work GPCI floor provided in section 1848(e)(1)(E) of the Act, which is set to expire prior to the implementation of the CY 2014 PFS.

F. Other Provisions of the Final Rule With Comment Period Regulation

1. Rebasing and Revising Medicare Economic Index

We estimate that there is no impact of the changes to the MEI for CY 2014.

2. Coverage of Items and Services furnished in FDA-Approved Investigational Device Exemption (IDE) Clinical Trials

We are finalizing our proposal of a transparent centralized review process that would be more efficient by reducing the burden for stakeholders. Once the IDE coverage process is centralized, there will be a single entity making the IDE coverage decision. This also eliminates duplicative reviews by Medicare local contractors and the numerous applications sent to contractors by stakeholders requesting IDE coverage. We believe that a centralized review process will not significantly reduce the number of IDE devices currently covered.

3. Ultrasound Screening for Abdominal Aortic Aneurysms

As discussed in section III.B. of this final rule with comment period, section 1861(s)(2)(AA) of the Act, with implementing regulations at § 410.19, authorizes Medicare coverage of ultrasound screening for abdominal aortic aneurysms (''AAA screening''). We are finalizing our proposal to modify § 410.19 to allow coverage of one-time AAA screening without receiving a referral as part of the IPPE, for beneficiaries that meet certain other eligibility criteria (a family history of AAA or, for men aged 65–75, a history of smoking). Approximately 45 percent of men aged 65–75 have a history of smoking. It is unknown how many individuals have a family history of AAA or how many beneficiaries will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

4. Modification to Medicare Coverage of Colorectal Cancer Screening

As discussed in section III.C. of this final rule with comment period, sections 1861(s)(2)(R) and 1861(pp)(1) of the Act, and implementing regulations at 42 CFR 410.37 authorize Medicare coverage of screening FOBT. We are finalizing our proposal to modify § 410.37(b) to allow attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists to furnish orders for screening FOBTs. Although there may be an increase in utilization, particularly in rural areas, it is unknown how many individuals will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

5. Ambulance Fee Schedule

As discussed in section III.D. of this final rule with comment period, section 604(a) through (c) of the ATRA require the extension of certain add-on payments for ground ambulance services and the extension of certain rural area designations for purposes of air ambulance payment. In addition, as discussed in section III.D. of this final rule with comment period, section 637 of the ATRA (which added section 1834(l)(15) of the Act) specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The ambulance extender provisions and the mandated 10 percent rate decrease discussed above are enacted through legislation that is self-implementing. We are finalizing our proposal to amend the regulation text at § 414.610 only to conform the regulations to these self-implementing statutory requirements. As a result, we are not making any policy proposals associated with these legislative provisions and there is no associated regulatory impact

6. Clinical Laboratory Fee Schedule

We are finalizing our proposal to add language to the Code of Federal Regulations to codify authority provided by statute and to establish a process under which we will systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount. We are also finalizing our proposal of a definition for the term technological changes. Adjustments made under the new process could both increase fee schedule amounts and provide for reductions in existing amounts. We cannot estimate a net impact at this time.

7. Liability for Overpayments to or on Behalf of Individuals including Payments to Providers or Other Persons

As discussed in section III.F. of this final rule with comment period, we are finalizing the regulation as proposed and changing the timeframe for the ''without fault'' presumptions from 3 years to 5 years. As a result, there would be an estimated savings of $0.5 billion over 10 years.

8. Physician Compare Web Site

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

9. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System (PQRS)

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are making additional proposals for 2014, this section modifies the impact statement provided for 2014 in the CY 2013 PFS final rule with comment period. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter ''the PQRS Reporting Experience''). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/*.

According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27 percent of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 remains accurate.

With respect to the estimate amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (that is, a bonus payment equal to 0.5 percent of the total allowed Part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27 percent of 1 million eligible professionals) 270,000 eligible professionals. At $1,059 per eligible professional, the PQRS would distribute approximately $286 million in incentive payments in 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would attempt to report PQRS quality measures data with the intention of earning the 2014 PQRS incentive, not simply to avoid the 2016 PQRS payment adjustment. Therefore, an eligible professionals or group practice would report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately $16/hour whereas the mean hourly wage for a computer analyst is approximately $40/hour.

For an eligible professional who wishes to participate in the PQRS as an individual, the eligible professional need not indicate his/her intent to participate. The eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in the PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in the PQRS would be approximately $80 ($16/hour × 5 hours).

With respect to an eligible professional who participates in the PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the existing HIPAA transaction 837–P and/or CMS Form 1500 (OCN: 0938–0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims will range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. Using an average labor cost of $40/hour, we estimate that time cost of reporting for an eligible professional via claims would range from $1.50 (2.25 minutes or 0.0375 hours × $40/hour) to $72.00 (108 minutes or 1.8 hours × $40/hour) per reported case. With respect to how many cases an eligible professional would report when using the claims-based reporting mechanism, we proposed that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional would report would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we are reducing the reporting threshold to 50 percent, we estimated that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimated that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from ($1.50/per reported case × 6 reported

cases) $9.00 to ($72.00/reported case × 6 reported cases) $432.

With respect to an eligible professional or group practice who participates in the PQRS via a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry, we believe there would be little to no burden associated for an eligible professional or group practice to report PQRS quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. Although we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, EHR data submission vendor, or qualified clinical data registry, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, EHR data submission vendor product, or qualified clinical data registry in our burden estimates.

Unlike eligible professionals who choose to report individually, we noted that eligible professionals choosing to participate as part of a group practice under the GPRO must indicate their intent to participate in the PQRS as a group practice. The total burden for group practices who submit PQRS quality measures data via the proposed GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for the PQRS, a group practice would need to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the PQRS as a GPRO, we believe it would take approximately 6 hours—including 2 hours to decide to participate in the PQRS as a GPRO, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials—for a group practice to be selected to participate in the PQRS GPRO for the applicable year. Therefore, we estimated that the cost of undergoing the GPRO selection process would be ($16/hour × 6 hours) $96. With respect to reporting, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimated the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimated that the report cost for a group practice to submit PQRS quality measures data for the proposed reporting options in an applicable year would be ($40/hour × 79 hours) $3,160.

Aside from the burden of eligible professionals and group practices participating in the PQRS, we believe that vendors of registries, qualified clinical data registries, direct EHR products, and EHR data submission vendor products incur costs associated with participating in the PQRS. Please note that we finalized requirements for a new reporting mechanism in this CY 2014 PFS final rule with comment period—the qualified clinical data registry. For purposes of these burden estimates, we believe that, at least in its initial stage, vendors of a qualified clinical data registry would have burden estimates similar to traditional registries, as we believe many of the vendors seeking to become qualified as a clinical data registry in the PQRS will be existing qualified registries.

With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years for PQRS, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process for both traditional registries and clinical data registries, we estimated that it will take a total of 10 hours—including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission—to become qualified to report PQRS quality measures data. Therefore, we estimated that it would cost a traditional registry and clinical data registry ($16.00/hour × 10 hours) $160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, we believe the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective of participating in the PQRS. Therefore, we believe there would be little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for the PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for a program year under the PQRS, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that we do not require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data.

In addition to the GPRO web interface, please note that we have established a new reporting mechanism that would be available to group practices comprised of 25–99 eligible professionals: the certified survey vendor. With respect to using a certified survey vendor, we believe there would be little to no burden associated for a group practice to report the CG CAHPS survey data to CMS, because the selected reporting mechanism submitted the quality measures data for the group practice. Although there may be start-up costs associated with purchasing a certified survey vendor, we believe that a group practice would not purchase a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of purchasing a certified survey vendor in our burden estimates.

TABLE 95—ESTIMATED COSTS FOR REPORTING PQRS QUALITY MEASURES DATA PER ELIGIBLE PROFESSIONAL

	Estimated hours	Estimated cases	Number of measures	Hourly rate	Total cost
Individual Eligible Professional (EP): Preparation	5.0	1	N/A	$16	$80.
Individual EP: Claims	1.8	6	9	40	3,888.
Individual EP: Registry	N/A	1	N/A	N/A	Minimal.
Individual EP: EHR	N/A	1	N/A	N/A	Minimal.
Group Practice: Self-Nomination	6.0	1	N/A	16	$96.
Group Practice: Reporting	79	1	N/A	40	$3,160.

TABLE 96—ESTIMATED COSTS PER VENDOR TO PARTICIPATE IN THE PQRS

	Estimated hours	Hourly rate	Total cost
Registry: Self-Nomination	10	$16	$160

10. Medicare EHR Incentive Program

Please note that the requirements for meeting the clinical quality measures (CQM) component of achieving meaningful use for the EHR Incentive Program in 2014 were established in a standalone final rule published on September 4, 2012 (77 FR 53968). The proposals contained in this CY 2014 PFS final rule with comment period merely propose alternative methods to report CQMs to meet the CQM component of achieving meaningful use for the EHR Incentive Program in 2014. We believe any impacts these proposals would have are absorbed in the impacts discussion published in the EHR Incentive Program final rule published on September 4, 2012.

11. Medicare Shared Savings Program

Please note that the requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule for the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67962). The proposals for the Medicare Shared Savings Program set forth in the CY 2014 final rule with comment period expand the incorporation of reporting requirements and incentive payments related to PQRS under section 1848 to include reporting requirements related to the payment adjustment. Since ACO participants and ACO provider/suppliers will not have to report PQRS separately to avoid the payment adjustment, this reduces the quality reporting burden for ACO participants participating in the Shared Savings Program. There is no impact for the additional proposals related to requirements for setting benchmarks or for scoring the CAHPS measure modules.

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

The changes to the Physician Feedback Program in section III.K. of this final rule with comment period would not impact CY 2014 physician payments under the Physician Fee Schedule. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the Physician Quality Reporting System to determine and understand how the value modifier could affect their payments.

13. Existing Standards for E-Prescribing under Medicare Part D and Identification

This section of the final rule with comment period imposes no new requirements because use of the official Part D e-prescreening standards; NCPDP SCRIPT 10.6, Formulary and Benefit 3.0 are voluntary, and as such, it will not have a significant economic impact on a substantial number of small entities, small rural hospitals or state, local, or tribal governments or on the private sector.

14. Chiropractic Services Demonstration

As discussed in section III.M. of this final rule with comment period, we are continuing the recoupment of the $50 million in expenditures from this demonstration in order to satisfy the BN requirement in section 651(f)(1)(B) of the MMA. We initiated this recoupment in CY 2010 and this will be the fifth and final year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup $10 million each year through adjustments to payments under the PFS for chiropractic CPT codes in CYs 2010 through 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. Although OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: $540 million in 2010; $520 million in 2011; and $580 million in 2012. In total, CMS recouped $32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately $580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately $11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately $44.4 million of the $50 million required for budget neutrality.

CMS plans to recoup the remaining funds, approximately $5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage.

G. Alternatives Considered

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

H. Impact on Beneficiaries

There are a number of changes in this final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of the changes, including the refinements of

the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the value-based payment modifier to adjust physician payment beginning in CY 2015; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS; and revisions to payment for Part B drugs will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 94, the CY 2013 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $108.05, which means that in CY 2013 a beneficiary would be responsible for 20 percent of this amount, or $21.61. Based on this final rule with comment period, using the current (CY 2013) CF of 34.0376, adjusted to 35.6446 to include budget neutrality, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 94, is $107.95, which means that, in CY 2014, the beneficiary coinsurance for this service would be $21.59.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 97 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this final rule with comment period. This estimate includes the CY 2014 incurred benefit impact associated with the estimated CY 2014 PFS conversion factor update based on the FY 2014 President's Budget baseline.Expenditures

TABLE 97—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED

Category	Transfers
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of $18.8 billion for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2014 Annualized Monetized Transfers	Estimated increase in payment of $286 million.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of $50 million for liability for overpayments to or on behalf of individuals including payments to providers or other persons.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 98—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2014 Annualized Monetized Transfers of beneficiary cost coinsurance.	−$29 million.
From Whom to Whom?	Beneficiaries to Physicians and Nonphysician Practitioners
Category	**Cost**
CY 2014 Annualized Monetized Cost to eligible professionals of Participating in the PQRS Program.	$66.6 million.

J. Conclusion

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

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

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

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

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by Reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1862(m), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395y(m), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.201 is amended by:
■ A. Revising paragraph (a)(2).
■ B. Adding paragraph (a)(3).
■ C. Revising paragraph (b).

The revisions and addition read as follows:

§ 405.201 Scope of subpart and definitions.

(a) * * *

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device.

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

ClinicalTrials.gov refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

■ 3. Section 405.203 is amended by revising paragraphs (a)(1) and (2) and (b) to read as follows:

§ 405.203 FDA categorization of investigational devices.

(a) * * *

(1) Category A (Experimental) devices.

(2) Category B (Nonexperimental/investigational) devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category A (Experimental) or Category B (Nonexperimental).

* * * * *

■ 4. Section 405.205 is amended by revising the section heading and paragraph (a)(1) to read as follows:

§ 405.205 Coverage of a Category B (Nonexperimental/investigational) device.

(a) * * *

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category B (Nonexperimental/investigational).

* * * * *

■ 5. Section 405.207 is amended by revising paragraphs (b)(2) and (3) to read as follows:

§ 405.207 Services related to a non-covered device.

* * * * *

(b) * * *

(2) Routine care items and services related to Category A (Experimental) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

(3) Routine care items and services related to Category B (Nonexperimental/investigational) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

■ 6. Section 405.209 is revised to read as follows:

§ 405.209 Payment for a Category B (Nonexperimental/investigational) device.

Payment under Medicare for a Category B (Nonexperimental/investigational) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

■ 7. Section 405.211 is revised to read as follows:

§ 405.211 Coverage of items and services in FDA-approved IDE studies.

(a) *Coverage of routine care items and services for Category A (Experimental) devices.* Medicare covers routine care items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in § 405.212 are met.

(b) *Coverage of Category B (Nonexperimental/investigational) IDE devices and routine care items and services.* Medicare may make payment for a Category B (Nonexperimental/investigational) IDE device and routine care items and services furnished in an FDA-approved Category B (Nonexperimental/investigational) IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria in § 405.212 are met.

(c) CMS (or its designated entity) must review the following to determine if the Medicare coverage IDE study criteria in § 405.212 are met for purposes of coverage of items and services described in paragraphs (a) and (b) of this section:

(1) FDA approval letter of the IDE.

(2) IDE study protocol.

(3) IRB approval letter.

(4) NCT number.

(5) Supporting materials, as needed.

(d) *Notification.* A listing of all CMS-approved Category A (Experimental) IDE studies and Category B (Nonexperimental/investigational) IDE studies shall be posted on the CMS Web site and published in the **Federal Register**.

■ 8. Section 405.212 is added to read as follows:

§ 405.212 Medicare Coverage IDE study criteria.

(a) For Medicare coverage of items and services described in § 405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria:

(1) The principal purpose of the study is to test whether the device improves

health outcomes of appropriately selected patients.

(2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

(3) The study results are not anticipated to unjustifiably duplicate existing knowledge.

(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.

(5) The study is sponsored by an organization or individual capable of successfully completing the study.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812 and 45 CFR part 46.

(7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

(8) The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.

(9) The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

(10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

(b) [Reserved]

■ 9. Section 405.213 is amended by revising paragraph (a)(1) to read as follows:

§ 405.213 Re-evaluation of a device categorization.

(a) * * *

(1) Any sponsor that does not agree with an FDA decision that categorizes its device as Category A (experimental) may request re-evaluation of the categorization decision.

* * * * *

■ 10. Section 405.350 is amended by revising paragraph (c) to read as follows:

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

* * * * *

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person must, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in which notice was sent to such individual that such amount had been paid.

■ 11. Section 405.355 is amended by revising paragraph (b) to read as follows:

§ 405.355 Waiver of adjustment or recovery.

* * * * *

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault will be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.

■ 12. Section 405.2413 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

The revision and addition reads as follows:

§ 405.2413 Services and supplies incident to a physician's services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a physician; and

* * * * *

■ 13. Section 405.2415 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

■ D. Revising paragraph (b).

The revision and addition reads as follows:

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

* * * * *

(b) The direct supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

* * * * *

■ 14. Section 405.2452 is amended by—

■ A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.

■ B. Adding new paragraph (a)(4).

■ C. Revising newly redesignated paragraph (a)(5).

■ D. Revising paragraph (b).

The revision and addition reads as follows:

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) * * *

(4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker or physician; and

* * * * *

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the federally qualified health center.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 15. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd).

§ 410.19 [Amended]

■ 16. In § 410.19(a) amend the definition of ''eligible beneficiary'' by

removing paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.

■ 17. Section 410.26 is amended by—
■ A. Revising paragraph (a)(1).
■ B. Redesignating paragraph (b)(7) and (8) as paragraph (b)(8) and (9), respectively.
■ C. Adding new paragraph (b)(7).

The revision and addition reads as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(1) *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(7) Services and supplies must be furnished in accordance with applicable State law.

* * * * *

■ 18. Section 410.37 is amended by revising paragraph (b) to read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(b) *Condition for coverage of screening fecal-occult blood tests.* Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

■ 19. Section 410.59 is amended by—
■ A. Adding paragraph (e)(1)(iv).
■ B. Revising paragraph (e)(2)(iv).
■ C. Adding paragraph (e)(2)(v).

The revision and additions reads as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(e) * * *

(1) * * *

(iv) Outpatient occupational therapy services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(2) * * *

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements.

* * * * *

■ 20. Section 410.60 is amended by—
■ A. Adding paragraph (e)(1)(iv).
■ B. Revising paragraph (e)(2)(v).
■ C. Adding paragraph (e)(2)(vi).
■ D. In paragraph (e)(3), removing the phrase ''or CAH''.

The additions and revision read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

* * * * *

(e) * * *

(1) * * *

(iv) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(2) * * *

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements.

* * * * *

■ 21. Section 410.71 is amended by revising paragraph (a)(2) to read as follows:

§ 410.71 Clinical psychologist services and services and supplies incident to clinical psychologist services.

(a) * * *

(2) Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of § 410.26 are met.

* * * * *

■ 22. Section 410.74 is amended by revising paragraph (b) to read as follows:

§ 410.74 Physician assistants' services.

* * * * *

(b) *Services and supplies furnished incident to a physician assistant's services.* Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of § 410.26 are met.

* * * * *

■ 23. Section 410.75 is amended by revising paragraph (d) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.

* * * * *

■ 24. Section 410.76 is amended by revising paragraph (d) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(d) *Services and supplies furnished incident to clinical nurse specialists' services.* Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of § 410.26 are met.

* * * * *

■ 25. Section 410.77 is amended by revising paragraph (c) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(c) *Incident to services: Basic rule.* Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.

* * * * *

■ 26. Section 410.78 is amended by revising paragraph (b) introductory text and paragraph (b)(4) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) *General rule.* Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every three days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) of this chapter and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group

kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

(4) Originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 27. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 28. Section 411.15 is amended by revising paragraphs (o)(1) and (2) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(o) * * *

(1) Categorized by the FDA as a Category B (Nonexperimental/investigational) device as defined in § 405.201(b) of the chapter; and

(2) Furnished in accordance with the coverage requirements in § 405.211(b).

* * * * *

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

■ 29. 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)).

■ 30. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§ 414.65 Payment for telehealth services.

(a) * * *

(1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one ''hands on'' visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of ''hands on'' services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

(i) *Emergency department or initial inpatient telehealth consultations.* The Medicare payment amount for emergency department or initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.

(ii) *Follow-up inpatient telehealth consultations.* The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

* * * * *

■ 31. Section 414.90 is revised to read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) 1848(a)—Payment Based on Fee Schedule.

(2) 1848(k)—Quality Reporting System.

(3) 1848(m)—Incentive Payments for Quality Reporting.

(b) *Definitions.* As used in this section, unless otherwise indicated—

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on PQRS quality measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

Certified survey vendor means a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

Covered professional services means services for which payment is made under, or is based on, the Medicare physician fee schedule as provided under section 1848(k)(3) of the Act and which are furnished by an eligible professional.

Direct electronic health record (EHR) product means an electronic health record vendor's product and version that submits data on PQRS measures directly to CMS.

Electronic health record (EHR) data submission vendor product means an entity that receives and transmits data on PQRS measures from an EHR product to CMS.

Eligible professional means any of the following:

(i) A physician.

(ii) A practitioner described in section 1842(b)(18)(C) of the Act.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Group practice means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

Group practice reporting option (GPRO) web interface means a web product developed by CMS that is used by group practices that are selected to participate in the group practice reporting option (GPRO) to submit data on PQRS quality measures.

Maintenance of Certification Program means a continuous assessment program, such as qualified American Board of Medical Specialties 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 communication skills, and professionalism. Such a program must include the following:

(i) The program requires the physician to maintain a valid unrestricted license in the United States.

(ii) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.

(iii) The program requires a physician to 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.

(iv) The program requires successful completion of a qualified maintenance of certification program practice assessment.

Maintenance of Certification Program Practice Assessment means an assessment of a physician's practice that—

(i) Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine.

(ii) Includes a survey of patient experience with care.

(iii) Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under paragraph (h) of this section and then to remeasure to assess performance improvement after such intervention.

Measures group means a subset of four or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

Physician Quality Reporting System (PQRS) means the physician reporting system under section 1848(k) of the Act for the reporting by eligible professionals of data on quality measures and the incentive payment associated with this physician reporting system.

Performance rate means the percentage of a defined population who receives a particular process of care or achieve a particular outcome for a particular quality measure.

Qualified clinical data registry means a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must perform the following functions:

(i) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.

(ii) Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients.

(iii) Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory participation in the clinical quality data registry.

(iv) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the PQRS qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide PQRS data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year, CMS reserves the right to disqualify a registry for reporting periods occurring in the subsequent year.

Reporting rate means the percentage of patients that the eligible professional indicated a quality action was or was not performed divided by the total number of patients in the denominator of the measure.

(c) *Incentive payments.* For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if—

(1) There are any quality measures that have been established under the PQRS that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and

(2) If the eligible professional (or in the case of a group practice under paragraph (j) of this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i) of this section for the group practice) to the Secretary data on such quality measures in accordance with the PQRS for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the

case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

(3) The applicable quality percent is as follows:

(i) For 2007 and 2008, 1.5 percent.

(ii) For 2009 and 2010, 2.0 percent.

(iii) For 2011, 1.0 percent.

(iv) For 2012, 2013, and 2014, 0.5 percent.

(4) For purposes of this paragraph (c)—

(i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

(iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the PQRS to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the PQRS group practice reporting option, the eligible professional cannot individually qualify for a PQRS incentive payment by meeting the requirements specified in paragraph (g) of this section.

(iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.

(5) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (g) of this section), if the eligible professional is satisfactorily participating (as determined under paragraph (h) of this section), in a qualified clinical data registry.

(d) *Additional incentive payment.* Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(iii) and (iv) of this section, must be increased by 0.5 percentage points.

(1) In order to qualify for the additional incentive payment described in paragraph (d) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures, or, for 2014, in lieu of satisfactory reporting, satisfactorily participates in a qualified clinical data registry for purposes of this section for the applicable incentive year.

(ii) Have such data submitted on their behalf through a Maintenance of Certification program that meets:

(A) The criteria for a registry (as specified by CMS); or

(B) An alternative form and manner determined appropriate by the Secretary.

(iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

(A) Participates in a maintenance of certification program for a year; and

(B) Successfully completes a qualified maintenance of certification program practice assessment for such year.

(2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information—

(i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(1)(iii) of this section, which may be in the form of a structural measure.

(ii) If requested by the Secretary, on the survey of patient experience with care.

(iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(e) *Payment adjustments.* For 2015 and subsequent years, with respect to covered professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) must be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this paragraph (e).

(1) The applicable percent is as follows:

(i) For 2015, 98.5 percent.

(ii) For 2016 and each subsequent year, 98 percent.

(2) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (h) of this section), if the eligible professional is satisfactorily participating, in a qualified clinical data registry.

(f) *Use of appropriate and consensus-based quality measures.* For measures selected for inclusion in the PQRS quality measure set, CMS will use group practice measures determined appropriate by CMS and consensus-based quality measures that meet one of the following criteria:

(1) Be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(2) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of quality measures applicable to services they furnish.

(g) *Use of quality measures for satisfactory participation in a qualified clinical data registry.* For measures selected for reporting to meet the criteria for satisfactory participation in a qualified clinical data registry, CMS will use measures selected by qualified clinical data registries based on parameters set by CMS.

(h) *Satisfactory reporting requirements for the incentive payments.* In order to qualify to earn a PQRS incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory reporting specified by CMS under paragraph (h)(3) of (h)(5) of this section for such year by reporting on either individual PQRS quality measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section, using

one of the reporting mechanisms specified in paragraph (h)(2) or (4) of this section, and using one of the reporting criteria specified in paragraph (h)(3) or (5) of this section.

(1) *Reporting periods.* For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 of such program year.

(ii) A 6-month period from July 1 through December 31 of such program year.

(A) For 2011, such 6-month reporting period is not available for EHR–based reporting of individual PQRS quality measures.

(B) For 2012 and subsequent program years, such 6-month reporting period from July 1 through December 31 of such program year is only available for registry-based reporting of PQRS measures groups by eligible professionals.

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional who wishes to participate in the PQRS must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Claims.* Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G–code at that time for reporting on individual PQRS measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) Although an eligible professional may attempt to qualify for the PQRS incentive payment by reporting on both individual PQRS quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one PQRS incentive payment per TIN/NPI combination for a program year.

(3) *Satisfactory reporting criteria for individual eligible professionals for the 2014 PQRS incentive.* An individual eligible professional who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures data in one of the following manners:

(i) *Via Claims.* For the 12-month 2014 PQRS incentive reporting period—

(A) Report at least 9 measures covering at least 3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 National Quality Strategy domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(B) [Reserved]

(ii) *Via Qualified Registry.* (A) For the 12-month 2014 PQRS incentive reporting period—

(1) Report at least 9 measures covering at least 3 of the National Quality Strategy domains report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional will be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(*2*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) For the 6-month 2014 PQRS incentive reporting period, report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(4) *Reporting mechanisms for group practices.* With the exception of a group

practice who wishes to participate in the PQRS using the certified survey vendor mechanism (as specified in paragraph (h)(4)(v) of this section), a group practice must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) *Web interface.* For 2013 and subsequent years, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For 2013 and subsequent years, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Certified survey vendors.* For 2014 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the incentive payments.

(vi) Although a group practice may attempt to qualify for the PQRS incentive payment by using more than one reporting mechanism (as specified in paragraph (g)(3) of this section), or reporting for more than one reporting period, the group practice will receive only one PQRS incentive payment for a program year.

(5) *Satisfactory reporting criteria for group practices for the 2014 PQRS incentive.* A group practice who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* (A) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

(B) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, for the 12-month 2014 PQRS incentive reporting period, the group practice must report all CG CAHPS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, or EHR data submission vendor.

(ii) *Via Qualified Registry.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the group practice, then the group practice must report 1–8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified survey vendor, in addition to the GPRO web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms.* For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 or more eligible professionals, report all CG CAHPS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.

(i) *Satisfactory participation requirements for the incentive payments for individual eligible professionals.* To qualify for the 2014 PQRS incentive using a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory participation as specified under paragraph (i)(3) of this section by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (i)(1) of this section, and using the reporting mechanism specified in paragraph (i)(2) of this section.

(1) *Reporting period.* For purposes of this paragraph, the reporting period is the 12–month period from January 1 through December 31.

(2) *Reporting Mechanism.* An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use a qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

(3) *Satisfactory participation criteria for individual eligible professionals for the 2014 PQRS incentive.* An individual eligible professional who wishes to qualify for the 2014 PQRS incentive through satisfactory participation in a qualified clinical data registry must report information on quality measures identified by the qualified clinical data registry in the following manner:

(i) For the 12-month 2014 PQRS incentive reporting period, report at least 9 measures designated for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure.

(ii) [Reserved].

(j) *Satisfactory reporting requirements for the payment adjustments.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, or a group practice must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual PQRS measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (j)(1) of this section, using one of the reporting mechanisms specified in paragraph (j)(2) or (4) of this section, and using one of the reporting criteria specified in section (j)(3) or (5) of this section.

(1) For purposes of this paragraph (j), the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1–December 31 that fall 2 years prior to the year in which the payment adjustment is applied, is also available.

(ii) [Reserved]

(2) *Reporting mechanisms for individual eligible professionals.* An individual eligible professional participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Claims.* Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual PQRS measures or measures groups.

(B) [Reserved]

(ii) *Registry.* Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Eligible professionals that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the PQRS using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional has performed services applicable to certain individual PQRS quality measures.

(3) *Satisfactory reporting criteria for individual eligible professionals for the 2016 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via Claims.* (A) For the 12-month 2016 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures covering at least 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1–8 measures covering 1–3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains; or

(*ii*) Report at least 3 measures covering at least 1 NQS domain, or, if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1–2 measures covering at least 1 NQS domain; and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(*2*) Measures with a 0 percent performance rate would not be counted.

(ii) *Via Qualified Registry.* (A) For the 12-month 2016 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures covering at least 3 of the National Quality Strategy domains; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least

3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains; or

(*ii*) Report at least 3 measures covering at least 1 of the NQS domains; or if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1 to 2 measures covering 1 National Quality Strategy domain for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures; or

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

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

(B) For the 6-month 2016 PQRS payment adjustment reporting period—

(*1*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) *Via EHR Direct Product.* For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(4) *Reporting mechanisms for group practices.* With the exception of a group practice who wishes to participate in the PQRS using the certified survey vendor mechanism, a group practice participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) *Web interface.* For the 2015 payment adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

(ii) *Registry.* For the 2015 subsequent adjustment and subsequent payment adjustments, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) *Direct EHR product.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

(iv) *EHR data submission vendor.* For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the group practice during the applicable reporting period.

(v) *Administrative claims.* For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Group practices that are administrative claims reporters must meet the following requirement for the payment adjustment:

(A) Elect to participate in the PQRS using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the group practice has performed services applicable to certain individual PQRS quality measures.

(vi) *Certified Survey Vendors.* For 2016 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the payment adjustment.

(5) *Satisfactory reporting criteria for group practices for the 2016 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* (A) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

(B) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the Web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, the group practice must also report all CG CAHPS survey measures via certified survey vendor.

(ii) *Via Qualified Registry.* (A) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 2 or more eligible professionals—

(*1*) Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or

If less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practices must report 1–8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted; or

(*2*) Report at least 3 measures, covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 3 measures covering at least 1 NQS domain apply to the group practice, then the group practice must report 1–2 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 3 measures covering at least 1 NQS domain via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether a group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR Direct Product.* For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR Data Submission Vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a Certified survey vendor, in addition to the GPRO Web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms.* For a group practice of 25 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report all CG CAHPS survey measures via a CMS-certified survey vendor and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO Web interface.

(k) *Satisfactory participation requirements for the payment adjustments for individual eligible professionals.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory participation as specified in paragraph (k)(3) for such year, by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section.

(1) Reporting period. For purposes of this paragraph, the reporting period is—

(i) The 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.

(ii) [Reserved.]

(2) *Reporting Mechanism.* An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

(3) Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2016 PQRS payment adjustment must report information on quality measures identified by the qualified clinical data registry in one of the following manners:

(i) For the 12-month 2016 PQRS payment adjustment reporting period—

(A) Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients; or

(B) Report at least 3 measures available for reporting under a qualified clinical data registry covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients.

(l) *Requirements for group practices.* Under the PQRS, a group practice must meet all of the following requirements:

(1) Meet the participation requirements specified by CMS for the PQRS group practice reporting option.

(2) Report measures in the form and manner specified by CMS.

(3) Meet other requirements for satisfactory reporting specified by CMS.

(4) Meet other requirements for satisfactory reporting specified by CMS.

(5) Meet participation requirements.

(i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the PQRS group practice reporting option for a program year, then for that program year the eligible professional must participate in the PQRS via the group practice reporting option.

(ii) If, for the program year, the eligible professional participates in the PQRS as part of a group practice (as identified by the TIN) that is not selected to participate in the PQRS group practice reporting option for that program year, then the eligible professional may individually participate and qualify for a PQRS incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

(m) *Informal review.* Eligible professionals or group practices may seek an informal review of the determination that an eligible professional or group practices did not satisfactorily submit data on quality measures under the PQRS, or, for individual eligible professionals, in lieu of satisfactory reporting, did not satisfactorily participate in a qualified clinical data registry.

(1) To request an informal review, an eligible professional or 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.

(i) All decisions based on the informal review will be final.

(ii) There will be no further review or appeal.

(n) *Limitations on review.* Except as specified in paragraph (i) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—

(1) The determination of measures applicable to services furnished by eligible professionals under the PQRS;

(2) The determination of satisfactory reporting; and

(3) The determination of any Physician Quality Reporting System incentive payment and the PQRS payment adjustment.

(o) *Public reporting of an eligible professional's or group practice's PQRS data.* For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) who satisfactorily submitted PQRS quality measures.

■ 32. Section 414.511 is added to subpart G to read as follows:

§ 414.511 Adjustments to the Clinical Laboratory Fee Schedule based on Technological Changes.

(a) CMS may make adjustments to the fee schedules as CMS determines are justified by technological changes.

(b) Technological changes are changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.

(c) CMS will propose and finalize any adjustments to the fee schedules as CMS determines are justified by technological changes in the **Federal Register**.

■ 33. Section 414.610 is amended by—

■ A. Revising paragraphs (c)(1)(ii) and (c)(5)(ii).

■ B. Adding paragraph (c)(8).

■ C. Revising paragraph (h).

The revisions and addition read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2013, ambulance services originating in:

(A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.

(B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2013, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(8) For ambulance services furnished on or after October 1, 2013 consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through June 30, 2013.

■ 34. Section 414.1210 is amended by revising paragraphs (a) and (c) to read as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) The value-based payment modifier is applicable:

(1) For the CY 2015 payment adjustment period, to physicians in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) For the CY 2016 payment adjustment period, to physicians in groups with 10 or more eligible professionals based on the performance period described at § 414.1215(b).

* * * * *

(c) *Group size determination.* The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups of physicians subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups of physicians are removed from the PECOS-generated list if, based on a claims analysis, the group of physicians did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period.

■ 35. Section 414.1215 is amended by adding paragraph (c) to read as follows:

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

* * * * *

(c) The performance period is calendar year 2015 for value-based payment modifier adjustments made in the calendar year 2017 payment adjustment period.

■ 36. Section 414.1220 is revised to read as follows:

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Groups of physicians subject to the value-based payment modifier (or individual eligible professionals within such groups) may submit data on quality measures as specified under the Physician Quality Reporting System using the reporting mechanisms for which they are eligible.

■ 37. Section 414.1225 is revised to read as follows:

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which groups of physicians or individual eligible professionals are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in § 414.1215, to the extent

a group of physicians or individual eligible professionals within such group submits data on such measures.

■ 38. Section 414.1235 is revised to read as follows:

§ 414.1235 Cost measures.

(a) *Included measures.* Beginning with the CY 2016 payment adjustment period, costs for groups of physicians subject to the value-based payment modifier are assessed based on a cost composite comprised of the following 6 cost measures (only the measures identified in paragraphs (a)(1) through (5) of this section are included for the value-based payment modifier for the CY 2015 payment adjustment period):

(1) Total per capita costs for all attributed beneficiaries.

(2) Total per capita costs for all attributed beneficiaries with diabetes.

(3) Total per capita costs for all attributed beneficiaries with coronary artery disease.

(4) Total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease.

(5) Total per capita costs for all attributed beneficiaries with heart failure.

(6) Medicare Spending per Beneficiary associated with an acute inpatient hospitalization.

(b) *Included payments.* Cost measures enumerated in paragraph (a) of this section include all fee-for-service payments made under Medicare Part A and Part B.

(c) *Cost measure adjustments.* (1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.

(2) The CMS–HCC model (and adjustments for ESRD status) is used to adjust standardized payments for the measures listed at paragraphs (a)(1) through (5) of this section.

(3) The beneficiary's age and severity of illness are used to adjust the Medicare Spending per Beneficiary measure as specified in paragraph (a)(6) of this section.

■ 39. Section 414.1240 is revised to read as follows:

§ 414.1240 Attribution for quality of care and cost measures.

(a) Beneficiaries are attributed to groups of physicians subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.

(b) For the Medicare Spending per Beneficiary (MSPB) measure, an MSPB episode is attributed to the group of physicians subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.

■ 40. Section 414.1255 is revised to read as follows:

§ 414.1255 Benchmarks for cost measures.

(a) For the CY 2015 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians that are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

(b) Beginning with the CY 2016 payment adjustment period, the cost measures of a group of physicians subject to the value-based payment modifier are adjusted to account for the group's specialty mix, by computing the weighted average of the national specialty-specific expected costs. Each national specialty-specific expected cost is weighted by the proportion of each specialty in the group, the number of eligible professionals of each specialty in the group, and the number of beneficiaries attributed to the group.

(c) The national specialty-specific expected costs referenced in paragraph (b) of this section are derived by calculating, for each specialty, the average cost of beneficiaries attributed to groups of physicians that include that specialty.

■ 41. Section 414.1260 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 414.1260 Composite scores.

* * * * *

(b) * * *

(1) * * *

(i) Total per capita costs for all attributed beneficiaries: Total per capita costs measure and Medicare Spending per Beneficiary measure; and

* * * * *

■ 42. Section 414.1270 is revised to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

(a) For the CY 2015 payment adjustment period:

(1) *Downward payment adjustments.* A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if—

(i) Such group neither self-nominates for the PQRS GPRO and reports at least one measure, nor elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(A) Such adjustment will be –1.0 percent.

(B) [Reserved].

(ii) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs; low quality and average costs; or average quality and high costs).

(A) Such adjustment will not exceed –1.0 percent as specified in § 414.1275(c)(1).

(B) [Reserved].

(2) *No payment adjustments.* There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either:

(i) Self-nominates for the PQRS GPRO and reports at least one measure; or

(ii) Elects the PQRS administrative claims option for CY 2013 as defined in § 414.90(h).

(3) *Upward payment adjustments.* If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a)(1) of this section and applied as specified in § 414.1275(c)(1).

(b) For the CY 2016 payment adjustment period:

(1) A downward payment adjustment of − 2.0 percent will be applied to a group of physicians subject to the value-based payment modifier if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) Such group does not self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2016 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS.

(2) For a group of physicians comprised of 100 or more eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(2).

(3) For a group of physicians comprised of between 10 and 99 eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(2), except that such adjustment will be 0.0 percent if the group of physicians is determined to be low quality/high cost, low quality/average cost, or average quality/high cost.

(4) If all of the eligible professionals in a group of physicians subject to the value-based payment modifier participate as individuals in the PQRS using a qualified clinical data registry or any other reporting mechanism available to them, and CMS is unable to receive quality performance data for those eligible professionals under that reporting mechanism, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

(5) A group of physicians subject to the value-based payment modifier will receive a cost composite score that is classified as ''average'' under § 414.1275(b)(2) if such group does not have at least one cost measure with at least 20 cases.

■ 43. Section 414.1275 is amended by revising paragraphs (a) and (c) and (d) introductory text to read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group of physicians subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

* * * * *

(c)(1) The following value-based payment modifier percentages apply to the CY 2015 payment adjustment period:

CY 2015 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+2.0x*	+1.0x*	+0.0
Average quality	+1.0x*	+0.0%	–0.5
Low quality	+0.0%	–0.5%	–1.0

*Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(2) The following value-based payment modifier percentages apply to the CY 2016 payment adjustment period:

CY 2016 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH

Quality/cost	Low cost	Average cost	High cost (percent)
High quality	+2.0x*	+1.0x*	+0.0
Average quality	+1.0x*	+0.0%	–1.0
Low quality	+0.0%	–1.0%	–2.0

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

(d) Groups of physicians subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2015 payment adjustment period elect the quality-tiering approach or for the CY 2016 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 44. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 45. Section 423.160 is amended by—

■ A. Revising paragraphs (b)(1)(i) through (iii).

■ B. Adding paragraphs (b)(1)(iv), (b)(5)(i) through (iii), and (c)(1)(vi).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(1) * * *

(i) Prior to April 1, 2009, the standards specified in paragraphs (b)(2)(i), (b)(3) and (4), (b)(5)(i), and (b)(6).

(ii) On or after April 1, 2009, to February 7, 2014, the standards specified in paragraphs (b)(2)(ii), (b)(3) and (4), (b)(5)(i) and (b)(6).

(iii) From February 8, 2014, until February 28, 2015, the standards specified in paragraphs (b)(2)(ii), (b)(3) and (4), (b)(5)(ii), and (b)(6).

(iv) From March 1, 2015, the standards specified in paragraphs (b)(2)(ii), (b)(3) and (b)(4), (b)(5)(iii), and (b)(6).

* * * * *

(5) * * *

(i) *Formulary and benefits.* Before The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(ii) *Formulary and benefits.* On The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0),

October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section), or The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporated by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(iii) Formulary and benefits. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporation by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

* * * * *

(c) * * *

(1) * * *

(vi) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 46. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

* * * * *

■ 47. Section 425.308 is amended by revising paragraph (e) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(e) *Results of claims based measures.* Quality measures reported using a CMS web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

■ 48. Section 425.502 is amended by revising paragraph (b)(2) to read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(b) * * *

(2)(i) CMS will define the quality benchmarks using fee-for-service Medicare data.

(ii) CMS will set benchmarks using flat percentages when the 60th percentile is equal to or greater than 80.00 percent.

(iii) CMS reserves the right to use flat percentages for other measures when CMS determines that fee-for-service Medicare data are unavailable, inadequate, or unreliable to set the quality benchmarks.

* * * * *

■ 49. Section 425.504 is amended by:

■ A. Revising the section heading.

■ B. Revising paragraphs (a)(1), (b) heading, and (b)(1).

■ C. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

(a) * * *

(1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using a CMS web interface, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System incentive under the Shared Savings Program.

* * * * *

(b) *Physician Quality Reporting System payment adjustment for 2015.* (1) ACOs, on behalf of their ACO providers/suppliers who are eligible professionals, must submit one of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

* * * * *

(c) *Physician Quality Reporting System payment adjustment for 2016 and subsequent years.* (1) ACOs, on behalf of their ACO providers/suppliers who are eligible professionals, must submit all of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(2) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

(3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2016 and subsequent years, each ACO provider/supplier who is an eligible professional, will receive a payment adjustment, as described in § 414.90(e) of this chapter.

(4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2016 and subsequent years, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.

(d) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 14, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 21, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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