Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

[CMS-1612-P]

Summary of Proposed Rule

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I. Introduction and Background

On July 3, 2014, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2015 and other revisions to Medicare Part B policies. The proposed rule is slated for publication in the July 11, 2014 issue of the *Federal Register*. As noted in the above table of contents, the proposed rule covers a wide range of issues. Noteworthy proposals this year include the following:

- The third comprehensive review and update of malpractice relative value units (MP RVUs);
- A proposal to transform all 10- and 90-day global surgery codes to 0-day global codes and re-value them accordingly, beginning in CY 2017, with separate payment to be made for post-procedure visits;
- Adoption of additional policies that will allow Medicare payment for chronic care management beginning January 1, 2015;
- Creation of an expedited local coverage determination (LCD) process applicable only to clinical diagnostic laboratory tests;
- Elimination of the current exclusion from reporting under the Open Payments (Sunshine Act) for drug and device manufacturer payments to support certain continuing education events;
- Significant changes affecting the Medicare Shared Savings Program, including adoption of a new methodology for rewarding improvement in performance by participating accountable care organizations (ACOs);
- Expansion of the value-based modifier (VM) to apply to all physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to solo practitioner starting in CY 2017 (with a CY 2015 performance period); and
- Increase the amount of payment at risk under the VM from 2.0 percent in CY 2016 to 4.0 percent in CY 2017.

These and other matters are discussed in more detail below. While the entire proposed rule is open for comment, this summary uses bold italics to highlight CMS requests for stakeholder input on specific issues.

In the proposed rule, CMS estimates that the conversion factor under the PFS for the first three months of CY 2015 would be $35.7977 (compared to the 2014 conversion factor of $35.8228). This estimate is based on a zero percent update (through March

31, 2015, as provided under the Protecting Access to Medicare Act of 2014 (PAMA) and the adjustments necessary to maintain budget neutrality for the policies in this proposed rule. CMS has chosen to apply this conversion factor to all of CY 2015 for purposes of completing its regulatory impact analysis. However, please note that, absent further Congressional action, a Medicare Sustainable Growth Rate (SGR)-induced reduction in the conversion would occur on April 1, 2015. In this regard, CMS again says it is committed to working with the Congress to permanently reform the SGR methodology for Medicare PFS updates.

On a specialty-specific basis, CMS estimates that the combined impact of the proposed rule would have the greatest negative effect on portable X-ray suppliers (-3 percent), radiation oncology (-4 percent), and radiation therapy centers (-8 percent), and the greatest positive effect on family practice (+2 percent), internal medicine (+2 percent), and independent laboratories (+3 percent).

The comment period on the proposed rule will close on September 2, 2014.

The addenda to the proposed rule along with other supporting documents are again only available through the Internet at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html, by clicking on the link at the left side of the screen titled, "PFS Federal Regulations Notices" and looking for item CMS-1612-P. Readers experiencing problems in accessing the addenda and other documents are advised to contact Larry Chan via e-mail at Larry.Chan@cms.hhs.gov.

II. Provisions of the Proposed Rule for PFS

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

1. Practice Expense Methodology.

CMS summarizes the history of the development of PE RVUs, the steps involved in calculating direct and indirect cost PE RVUs, and other related matters.

With respect to the formula for calculating equipment cost per minute, ***CMS solicits comments regarding reliable data on maintenance costs that vary for particular equipment items, in light of past stakeholders' suggestion that the maintenance factor assumption should be variable, rather than the current, uniform 0.05. CMS also solicits comments on whether the PE methodology should be adjusted to include equipment costs that do not vary based on equipment time, such as usage fees and other per-use equipment costs.***

2. Changes to Direct PE Inputs for Specific Services

CMS proposes to accept the American Medical Association/Special Society Relative Value Update Committee (RUC) recommendation to adjust clinical labor minutes for 17

procedures listed in Table 5 of the proposed rule for post-procedure moderate sedation monitoring and post-procedure monitoring. The RUC recommended 15 minutes of registered nurse (RN) time for one hour of monitoring following moderate sedation and 15 minutes of RN time per hour for post-procedure monitoring (unrelated to moderate sedation).

CMS acknowledges receipt of a RUC recommendation to modify PE inputs included in the standard moderate sedation package to include a stretcher and notes that the RUC did not recommend immediate changes to PE inputs for codes but indicated that its future recommendations would include the stretcher for procedures including moderate sedation. CMS proposes to include a stretcher for the same length of time as the other equipment items in the moderate sedation package and apply the revised moderate sedation package as it reviews relevant codes through future notice and comment rulemaking. However, ***CMS invites comment on whether the stretcher time should be allocated with more granularity than the equipment costs are allocated to other similar items (noting that the RUC said it intended to consider whether the stretcher might be available for other patients during a portion of a given procedure).***

CMS also proposes to accept the RUC recommendation to remove the 30 film supply and equipment items associated with film technology (listed in Table 6 of the proposed rule) since these are no longer a typical resource input in providing digital imaging services. CMS acknowledges that this negatively affects portable X-ray suppliers, diagnostic testing facilities, and interventional radiology. The RUC also recommended that the Picture Archiving and Communication System (PACS) equipment be included for these imaging services since these items are now typically used in furnishing imaging services. However, since CMS did not receive any invoices for the PACS system, it proposes to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation as a direct expense. CMS adds that for the 31 services that already contain ED021, it proposes to retain the time that is currently included in the direct PE input database. For the remaining services that are valued in the nonfacility setting, CMS proposes to allocate the full clinical labor intraservice time to ED021, except when there is no clinical labor, in which case CMS proposes to allocate the intraservice work time to ED021. For services valued only in the facility setting, CMS proposes to allocate the post-service clinical labor time to ED021, since the film supply and/or equipment inputs were previously associated with the post-service period.

CMS notes that the RUC exempted certain procedures from its film supply and equipment recommendation because (a) the dominant specialty indicated that digital technology is not yet typical or (b) the procedure only contained a single input associated with film technology, and it was determined that the sharing of images, but not actual imaging, may be involved in the service. However, CMS rejects recommendations based on dominant specialty input, arguing that migration to digital technology will be typical for most if not all imaging services before the proposed change to digital inputs would take effect beginning January 1, 2015. CMS also proposes to remove film supply and equipment inputs from 56 codes not covered by the

RUC recommendation (e.g., HCPCS code 28293, Correction of bunion, and HCPCS code 70310, X-ray exam of teeth). ***CMS seeks comment on whether the computer workstation, which it proposes to use as a proxy for the PACS workstation, is appropriate for these 56 codes, or whether an alternative input should be used.***

CMS further agrees with the RUC that reviewing and adjusting the clinical labor times associated with film technology for each relevant code would be difficult and labor-intensive (since the direct PE input database does not allow for a comprehensive adjustment of the clinical labor time based on changes in particular clinical labor tasks). In this regard, CMS says it is considering revising the direct PE input database to include task-level clinical labor time information for every code and refers readers to the supporting data files for the direct PE inputs, which include public use files that display clinical labor times as allocated to each individual clinical labor task for a sample of procedures. ***CMS seeks comments on the feasibility of modifying the direct PE input database in this fashion in order to enable the agency to more accurately allocate equipment minutes to clinical labor tasks in a more consistent and efficient manner,*** but emphasizes that it is not proposing to make any changes to PE inputs for CY 2015 based on the proposed modification to the design of the direct PE input database.

Because it appears that the typical mammography service is furnished using digital technology, CMS proposes to delete the mammography G-codes (G0202, G0204, and G0206) for CY 2015 and to pay all mammography using CPT codes 77055, 77056, and 77057. However, because CMS has concerns about whether the current values for the CPT codes accurately reflect the resource inputs associated with furnishing the services, it proposes to value the CPT codes using the RVUs previously established for the G-codes. CMS also notes that it is proposing these CPT codes as potentially misvalued and requesting that the RUC and other interested stakeholders review these services in terms of appropriate work RVUs, work time assumptions and direct PE inputs.

CMS further proposes to remove the radiation treatment vault as a direct PE input from 14 radiation treatment procedures listed in Table 8 of the proposed rule because it believes that the specific structural components required to house the linear accelerator are similar in concept to components required to house other medical equipment, such as expensive imaging equipment, and because it is difficult to distinguish the cost of the vault from the cost of the building. CMS notes that the vault construction would instead be accounted for in the indirect PE methodology. CMS acknowledges that this proposed change negatively affects radiation oncology and radiation treatment centers.

CMS proposes to correct two clerical errors. The first would correct the clinical labor type for CPT code 77293 (Respiratory Motion Management Simulation), substituting medical physicist for audiologist. The second would move RN time for CPT codes 33620 (Apply r&l pulm art bands), 33621 (Transthor cath for stent), and 33622 (Redo compl cardiac anomaly) from the nonfacility setting to the facility setting where the code is valued.

CMS also proposes to correct times for services for which total work time did not equal the sum of the component parts, for a subset of services for which pre-positioning, pre-evaluation, and pre-scrub-dress-wait times were inadvertently transposed, and for a series of interim final codes for which there were minor discrepancies between the work time file and the way CMS addressed these codes in the preamble text.

In response to requests received in 2013, CMS proposes to update the price of SD216 (catheter, balloon, esophageal or rectal (graded distension test)) from $217 to $237.50, and to update the price of SL196 (kit, HER-2/neu DNA Probe) from $105 to $144.50, based on submitted invoices. CMS notes, however, that it can be difficult to ascertain whether the prices on particular invoices are typical, ***and adds that it continues to seek stakeholder input on the best approach to using the small sample of invoices that are provided to the agency.*** CMS also reminds stakeholders that any increases in price inputs for particular supply items result in corresponding decreases to the relative values for all other direct PE inputs (because PFS payment rates are developed within a budget neutral, relative value system). CMS also agrees with RUC recommendations to update the prices associated with two kits/packs to reflect the addition of supply items. First, CMS proposes to increase the price of SA042 (pack, cleaning and disinfecting, endoscope) from $15.52 to $17.06 to reflect the addition of supply item SJ009 (basin, irrigation). Second, CMS proposes to increase the price of SA019 (kit, IV starter) from $1.37 to $1.60 to reflect the addition of supply item SA044 (underpad 2 ft. x 3 ft. (Chux)).

CMS also proposes to accept a RUC recommendation to create a new direct PE input standard supply package "Imaging w/contrast, standard package" for contrast enhanced imaging, with a price of $6.82. The items for this package are listed in Table 9 of the proposed rule ***but CMS seeks comment on whether all of these items are used in the typical case.***

CMS proposes to recognize only the CPT codes for payment of stereotactic radiosurgery services (SRS), CPT codes 77372 and 77373, and to delete the G-codes used to report robotic delivery of SRS (G0339 and G0340), saying that it has no indication that the direct PE inputs included in the CPT codes do not reflect the typical resource inputs involved in furnishing an SRS service.

CMS also proposes to include equipment item EQ358 (Sleep capnograph, polysomnography (pediatric)) for CPT codes 95782 and 95783 since the agency understands that capnography is a required element of sleep studies for patients younger than 6 years. CMS proposes a price of $4,534.23 for EQ358, based on one invoice, and to allocate this equipment item to 95782 for 602 minutes and to 95783 for 647 minutes.

Finally, ***CMS seeks comment regarding whether it is appropriate to have nonfacility PE RVUs for CPT codes 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention;***

initial vessel) and 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel), and if so what inputs should be assigned to these codes.

3. Using OPPS and ASC Rates in Developing PE RVUs

CMS acknowledges proposing but not finalizing during CY 2014 rulemaking a policy limiting the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. CMS adds that it is not proposing a similar policy for the CY 2015 PFS and that if it did do so in future rulemaking, it would consider all of the comments received on its previous proposal.

CMS notes, however, that it continues to believe that there are various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated. CMS adds that in response to section 220(a) of PAMA, Publ. L. 113-93, it will be exploring ways of collecting better and updated resource data from physician practices, including those that are provider-based, and other non-facility entities paid under the PFS. CMS says that such efforts will be challenging given the wide variety of practices and likely impose some burden on eligible professionals. CMS notes that through a validation contract, it has been gathering time data directly from physician practices, from which it has learned much about the challenges of gathering data directly from physician practices.

CMS further notes that section 220 of PAMA provides authority to use alternative approaches to establish PE RVUs, including the use of data from other suppliers and providers, and that the agency is exploring how best to exercise this authority. ***CMS seeks comment on the possible uses of the Medicare hospital outpatient cost data in potential revisions of the PFS PE methodology, as means to validate or, perhaps, in setting the relative resource cost assumptions within the PFS PE methodology. CMS is particularly interested in comments identifying other broad-based, auditable, mechanisms for data collection that could be considered under the authority provided under section 220(a) of PAMA.***

CMS also says it continues to seek a better understanding regarding the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments. CMS adds that as more physician practices become hospital-based, it is difficult to know which PE costs typically are actually incurred by the physician, which are incurred by the hospital, and whether Medicare's bifurcated site-of-service differential adequately accounts for the typical resource costs given these relationships. CMS proposes to create a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital, ***but nonetheless invites additional comment on whether such a modifier is the best mechanism for***

collecting service-level information.[1] The modifier would be reported on both the CMS-1500 claim form for physicians' services and the UB-04 (CMS form 1450) for hospital outpatient claims. CMS further proposes to begin collecting this information on January 1, 2015 and cites section 1834(c)(2)(M), as added by section 220(a) of PAMA, as its authority for doing so.

B. Potentially Misvalued Services Under the Physician Fee Schedule

1. Validating RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(L) of the Act requires the Secretary to establish a formal process to validate RVUs under the PFS. CMS entered into two contracts to develop validation models for RVUs. The first contract is with the Urban Institute. The key focus of this project is to collect data from several practices for services selected by the contractor to develop objective time estimates, which will be compared with current time values used in the PFS. CMS reports that the Urban Institute has encountered numerous challenges in collecting data and collection of time data has begun. CMS plans to make the final report available on the CMS website.

The second contract is with the RAND Corporation and uses available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. For this project, RAND will use a representative set of CMS-provided codes to test the model. CMS anticipates a report by the end of this year and will make the report available on the CMS website.

2. CY 2015 Identification and Review of Potentially Misvalued Services

a. Public Nomination

During the comment period for the 2014 PFS final rule, CMS received nominations and supporting documentation for two codes: CPT code 41530 and CPT code 99174.

- CPT code 41523 (submucosal ablation of the tongue base, radiofrequency). The nominator stated that this code is misvalued because there have been changes in the PE items (specifically, the probes) used in performing this service. CMS is proposing this code as a potentially misvalued code.
- CPT code 99174 (instrument-based ocular screening). The nomination stated that this code is misvalued because of outdated equipment inputs and changes in direct PE inputs. Since this code in non-covered on the PFS and CMS only considers nomination of active codes that are covered by Medicare at the time of nomination, CMS is not proposing CPT code 99174 as a potentially misvalued code.

[1] Requirements for determining whether a facility or organization has provider-based status are specified in §413.65.

b. Potentially Misvalued Codes

1. Review of High Expenditure Services Across Specialties with Medicare Allowed Charges of $10 Million or More

Section 220(c) of PAMA expanded the list of categories of codes the Secretary is directed to examine and included codes that account for the majority of spending under the PFS. Table 10 of the proposed rule (reproduced below) lists the 65 codes identified through the high expenditure specialty screen. CMS notes they excluded codes that have been reviewed since CY 2009, codes with fewer than $10 million in allowed charges, and codes that describe anesthesia or E/M services.

TABLE 10: Proposed Potentially Misvalued Codes Identified Through High Expenditure Specialty Screen

HCPCS	Short Descriptor
11100	Biopsy skin lesion
11101	Biopsy skin add-on
11730	Removal of nail plate
11750	Removal of nail bed
14060	Tis trnfr e/n/e/l 10 sq cm/<
17110	Destruct b9 lesion 1-14
31575	Diagnostic laryngoscopy
31579	Diagnostic laryngoscopy
36215	Place catheter in artery
11100	Biopsy skin lesion
11101	Biopsy skin add-on
11730	Removal of nail plate
11750	Removal of nail bed
14060	Tis trnfr e/n/e/l 10 sq cm/<
17110	Destruct b9 lesion 1-14
31575	Diagnostic laryngoscopy
31579	Diagnostic laryngoscopy
36475	Endovenous rf 1st vein
36478	Endovenous laser 1st vein
36870	Percut thrombect av fistula
51720	Treatment of bladder lesion
51728	Cystometrogram w/vp
51798	Us urine capacity measure
52000	Cystoscopy
55700	Biopsy of prostate

65855	Laser surgery of eye
66821	After cataract laser surgery
67228	Treatment of retinal lesion
68761	Close tear duct opening
71010	Chest x-ray 1 view frontal
71020	Chest x-ray 2vw frontal&latl
71260	Ct thorax w/dye
73560	X-ray exam of knee 1 or 2
73562	X-ray exam of knee 3
73564	X-ray exam knee 4 or more
74183	Mri abdomen w/o & w/dye
75978	Repair venous blockage
76536	Us exam of head and neck
76700	Us exam abdom complete
76770	Us exam abdo back wall
76775	Us exam abdo back wall lim
77263	Radiation therapy planning
77334	Radiation treatment aid(s)
78452	Ht muscle image spect mult
88185	Flowcytometry/tc add-on
91110	Gi tract capsule endoscopy
92136	Ophthalmic biometry
92250	Eye exam with photos
92557	Comprehensive hearing test
93280	Pm device progr eval dual
93306	Tte w/doppler complete
93351	Stress tte complete
93978	Vascular study
94010	Breathing capacity test
95004	Percut allergy skin tests
95165	Antigen therapy services
95957	Eeg digital analysis
96101	Psycho testing by psych/phys
96118	Neuropsych tst by
96372	Ther/proph/diag inj sc/im
96375	Tx/pro/dx inj new drug addon
96401	Chemo anti-neopl sq/im
96409	Chemo iv push sngl drug
97032	Electrical stimulation

97035	Ultrasound therapy
97110	Therapeutic exercises
97112	Neuromuscular reeducation
97113	Aquatic therapy/exercises
97116	Gait training therapy
97140	Manual therapy 1/> regions
97530	Therapeutic activities
G0283	Elec stim other than wound

2. Epidural Injection and Fluoroscopic Guidance (CPT codes 62310, 63211, 63218, 63219, 77001, 77002, 77003)

For CY 2014, CMS established interim final values for four epidural injection procedures (CPT codes 62310, 63211, 63218, 63219) that resulted in reductions from the CY 2013 rates. CMS states that they established work RVUs below those recommended by the RUC because they did not believe the RUC recommendations accounted for the reduction in time it takes for these services as compared to when they were last valued. CMS notes they received thousands of comments objecting to the interim final values. Comments that addressed the accuracy of the inputs CMS used in calculating the rates objected to CMS assuming that the time information was correct and that CMS' work RVUs were based only on time and failed to include other factors such as the intensity and complexity of service. A few commenters stated that critical PE inputs were not included. Several commenters objected to the use of the interim final process for validating these codes and cited the lack of opportunity for public comment before the reimbursement took effect (see discussion in section II.F of this summary).

In response to comments, CMS states that they need to reassess their validation of these codes, which will require additional information. CMS discusses that these epidural codes are frequently billed with imaging guidance; the data indicate that fluoroscopic guidance is both typically used and typically reported separately in combination with the epidural injection codes. CMS believes it would be appropriate to bundle the injection and imaging guidance codes and that the inputs for image guidance be included in the valuation of the epidural injection codes, similar to the transforminal and paravertebral injection CPT codes.

CMS seeks comments on the following proposals:

- Include CPT codes 62310, 62311, 2318 and 63219 on the potentially misvalued code list and obtain information to support their valuation with image guidance included in the service.
- Use the CY 2013 input values (work RVUS, work times, and direct PE inputs) for CPT codes 62310, 62311, 62318 and 62319 to establish payments for 2015.
- Prohibit the billing of image guidance codes in conjunction with these four epidural injection codes. CMS states that the proposed PE inputs for the epidural injection codes include items that are specifically related to image

guidance (e.g. radiographic fluoroscopic room) and that separate reporting would overestimate the resources used in furnishing these two services together.

3. Percutaneous Implantation of Neurostimulator Electrode Array (CPT codes 64553 (for cranial nerve) and 64555 (for peripheral nerve, excluding sacral nerve)

In response to a question about the direct PE inputs used when these services were performed in the nonfacility setting, CMS is nominating these codes as potentially misvalued. CMS states they want to determine whether or not there are nonfacility direct PE inputs that are not included in the direct PE inputs that are typical supply costs for these services.

4. Mammography (CPT codes 77055, 77056, and 77057 and HCPCS codes G0202, G0204, and G0206)

Medicare currently pays for mammography services through both CPT codes and HCPCS G-codes. (The CPT codes were designed to be used for film or digital mammography and the HCPCS G-codes were created in response to special payment rules for digital mammography in the Medicare BIPA of 2000.)
CMS notes that the Medicare data indicates the overwhelming majority of all mammography is digital (this supports the RUC recommendation previously discussed about the direct PE input for the mammography CPT codes).

CMS seeks comments on the following proposals:

- Using CPT codes 77055, 77056, and 77057 to report mammography to Medicare regardless of whether film or digital technology is used;
- Deleting HCPCS G-codes G0202, G0204, and G0202;
- Valuing the CPT codes using the values established for the digital mammography G-codes; and
- Including CPT codes 77055, 77056 and 77057 on the list of potentially misvalued codes because they have not been reviewed since they were created in CY 2002.

5. Abdominal Aortic Aneurysm Ultrasound Screening – G0389

In 2007, CMS created HCPCS code G0389 and set the RVUs at the same level as CPT code 76775 (ultrasound, retroperitoneal; limited). In the CY 2014 PFS proposed rule, based on a RUC recommendation, CMS proposed to replace the ultrasound room included as direct PE input for CPT code 76775 with a portable ultrasound unit. CMS notes that in the proposed rule's preamble they did not discuss the applicability of this change to G0389 and did not receive any comments on G0389. Subsequent to the publication of the CY 2014 PFS final rule, a stakeholder stated that the type of equipment typically used in furnishing G0389 is different than that used for CPT code 76775, the time involved is different between the two codes, and that different physician specialties perform these services. The stakeholder suggested an alternative crosswalk of CPT code 76705 (ultrasound, abdominal; limited).

CMS seeks comments on the following proposals:

- Including G0389 as a potentially misvalued code and seek recommendations for work RVU, time, and the direct PE inputs;
- Maintaining the work RVU for this code and reverting to the same PE RVUs used for 2013, adjusted for budget neutrality; and
- Proposing MP RVUs based on the five-year review update process (discussed in section II.C of this summary).

6. Prostate Biopsy Codes (HCPCS codes G0416, G0418, and G0419 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method))

For CY 2014, CMS modified the code descriptors for the prostate biopsy codes so that they could be used for any method and the specific code used depended on the number of specimens. Based on discussion with stakeholders and reviews of both medical literature and Medicare claims data, CMS is proposing to use only one code to report biopsy pathology services.

CMS seeks comments on the following proposals:

- Revising HCPCS code G0416 to report all prostate biopsy pathology services, regardless of the number of specimens. Based on a review of Medicare data, CMS notes that G0416 (10 – 20 specimens) represents the majority of all Medicare claims submitted for the 4 G-codes;
- Using the existing values for G0416 for CY 2015.
- Including G0416 as a potentially misvalued code for CY 2015; and
- Deleting codes G0417, G0418, and G0419.

7. Obesity Behavioral Group Counseling (GXXX2 and GXXX3)

In response to questions about the coding for obesity behavioral counseling, CMS is creating two new codes for the reporting and payment of group behavioral counseling for obesity:

- GXXX2 – Face-to-face behavioral counseling for obesity, group (2-4), 30 minutes) and
- GXXX3 – Face-to-face behavioral counseling for obesity, group (5-10), 30 minutes.

The coverage requirements for these services would be the same as described in the National Coverage Determination for Intensive Behavioral Therapy for Obesity.

CMS states that the services described by the new codes would require similar per minute work and intensity inputs G0447 (Face-to-face behavioral counseling for obesity, 15 minutes) and scaled the work RVUs of G0447 to reflect the time difference and the typical number of beneficiaries per session. CMS also notes that the services described by the new codes will be billed per beneficiary receiving the service.

CMS seeks comments on the following proposals:

- A work RVU of 0.23 with a work time of 8 minutes for GXXX2 and a work RVU of 0.10 with a work time of 3 minutes for GXXX3;
- Using the direct PE inputs for G0447, prorated to account for the differences in time and the number of beneficiaries described by the new codes; and
- Crosswalking the malpractice risk factor from HCPCS code Go447 to both new codes.

4. Improving the Valuation and Coding of the 10- and 90- Day Global Surgical Package

a. Concerns with the 10- and 90-Day Global Packages

CMS acknowledges the importance of bundled payments as a mechanism to incentivize high-quality, efficient care and the need to have accurate values for PFS services used as the building blocks for bundled payments. CMS states that although the PFS global codes appear to be similar to other Medicare bundled payments, there are significant differences from other bundled payments. As discussed below, CMS raises several concerns that they believe create substantial barriers to accurately valuing 10- and 90-day global packages relative to other PFS services.

1. Fundamental Limitations in the Appropriate Valuation of Global Packages with Post-operative Days

CMS notes that their valuation methodology for PFS services generally relies on the assumptions about the resources used in furnishing the "typical case" for each individual service instead of relying on actual data on the costs of furnishing services. Therefore, the RVUs for a global code should reflect the typical number and level of E/M services furnished in connection with the surgical procedure. CMS discusses how any inaccuracy in the assumptions of the typical number or kind of services in the post-operative period are amplified in codes with long post-operative periods and skews both the relative accuracy of RVUs for individual global codes and Medicare payment to individual physicians. When a global surgical package includes more or a higher level of E/M services than are actually furnished in the typical post-operative period, the Medicare payment is based on an overestimate of the quantity or level of service furnished, not just an overestimation of the resources involved in furnishing an individual service. (CMS notes the converse is true if the global surgical package is based on fewer or a lower level of services for a particular code.)

2. Questions Regarding Accuracy of Current Assumptions

CMS cites several OIG reports indicating that the values included in the post-operative global codes may not reflect the typical number and level of post-operative E/M visits actually furnished. CMS does acknowledge that under the global surgery payment policy it is not necessary for a surgeon to report the individual E/M services actually furnished during the global surgical period and that they lack objective data to assess

the OIG findings. In the CY 2013 PFS proposed rule, CMS sought public comment about how to collect data about the post-operative E/M services. Commenters provided a wide range of suggestions, including using the RUC survey data and eliminating the 10- and 90-day global codes. Commenters were also concerned that global surgical payments created payment policy disparities (discussed below).

3. Limitations on Appropriate Future Validation of 10- and 90-Day Global Surgery Codes

CMS states that even if they could obtain objective information about the typical case, the ongoing valuation of individual codes with post-operative periods would not be straightforward and would require frequent updates about the number and level of visits in the post-operative periods to account for ongoing changes in the delivery of health care.

4. Unwarranted Payment Disparities

CMS notes that in response to the CY 2013 PFS proposed rule, some commenters raised concerns that global surgery packages contributed to unwarranted payment disparities between physicians who do and do not furnish these services. Commenters noted that Medicare pays physicians during the post-surgical periods regardless of whether the services are actually furnished or the post-operative care is transferred to another physician while other physicians are only paid for E/M services actually furnished. Other commenters noted that E/M services in the global period generally included higher PE values than the same E/M services when they are billed separately and provided two reasons for this difference. First, a different mix of PE inputs is included in the direct PE inputs for a global period E/M service as compared to a separately billed E/M service. Second, because the specialty mix is generally not as broad a range of specialties that report separate individual E/M services the indirect PE allocated to the E/M visits included in the global surgical codes are higher than those allocated to separately furnished E/M visits. Commenters were also concerned that the PE RVUs for global surgery codes assumed that all outpatient visits occurred in the higher-paid non-facility office setting, when many of these visits are likely to be furnished in provider-based departments, which would be paid at the lower, PFS rate if they were billed separately.

5. New Payment Models

CMS notes that RVUs to establish PFS payments are critical inputs for numerous new payment models, including bundled payments to practitioners or payments for episodes of care. They raise concerns that inaccurate assumptions regarding resource costs associated with global surgical periods are potential obstacles to payment bundles designed to foster efficiency and quality of care.

b. Proposed Transition of 10-and 90- Global Packages into 0-day Global Packages

CMS states using their existing methodologies and the available data, they cannot address all the issues inherent in establishing values for the 10- and 90- day global surgical packages and **proposes to transition, over several years, all 10- and 90-day global surgical codes to 0-day global surgical codes**. Medically reasonable and necessary visits would be billed separately during the pre and post-operative periods outside the day of the surgical procedure. Pending the availability of data on which to base updated values for the global codes, CMS is proposing to make the transition for current 10-day global codes in CY 2017 and for current 90-day global codes in CY 2018.

CMS believes a transition to 0-day global codes would:

- Increase the accuracy of PFS payment by setting payment rates for individual services based more closely on the typical resources used;
- Avoid potential duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner;
- Eliminate disparities between the payment for E/M services in the global periods and those furnished individually;
- Maintain the same-day policy of including pre-and post-operative services in the 0-day global; and
- Facilitate availability of more accurate data for new payment models and quality research.

CMS discusses several alternatives they considered to address the concerns about global surgical packages including obtaining data to revalue the codes and also options for altering the PE methodology. CMS also considered both identifying all the 3,000 global surgery codes as potentially misvalued and making changes in the PE methodology. CMS concludes that none of the alternatives would accommodate the rapid changes in medical practice and that the values for the codes would be quickly out dated.

CMS seeks specific comments on how to efficiently obtain accurate date to:

- Revalue or adjust the work RVUs for the current global codes to reflect the typical resources involved in furnishing the services, including the pre-and post-operative care on the day of the procedure; and
- Determine the number and level of post-operative E/M visits CMS also seeks information on the extent to which individual physicians or practices may currently maintain their own data on services furnished during the post-operative period, and how CMS might collect and objectively evaluate this data.

CMS does not believe it is practical to survey time and intensity information on each of the surgical procedures and the number and level of post-service E/M visits and suggests other methods of valuation including:

- Using the current potentially misvalued code process to identify and value the relatively small number of codes that represent the majority of the volume of

services that are currently reported with codes with post-operative periods and then adjust the aggregate RVUs to account for the number of visits. CMS would then use magnitude estimation to value the remaining codes in the family;
- Value one code within a family through the current valuation process and then use magnitude estimation to value the remaining services in the family; and
- Survey a sample of codes across all procedures to create an index that could be used to value the remaining codes.

CMS also requests input on the best approach to achieve this proposed transition including:

- How to mitigate that separate payment of E/M visits does not incentivize otherwise unnecessary office visits during the post-operative period;
- Whether the effective date for the transition to 0-day global periods should be staggered across families of codes or other categories;
- A faster or slower transition; and
- How to determine appropriate valuation for new, revised or potentially misvalued 10- or 90-day global codes before implementation of this proposal.

5. Improving the Valuation of the Global Package

In response to the AMA identification of global surgery codes missing postoperative hospital inpatient and discharge data due to an inadvertent error, CMS is proposing to include a corrected number of visits for 61 global surgery codes and a corresponding correction in the total times associated with these codes (See Table 11 in the proposed rule, Proposed Work Time Changes in Selected Global Surgical Package Visits).

6. Valuing Services that Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

CPT has determined that moderate sedation is an inherent part of furnishing the procedure for the more than 300 diagnostic and therapeutic procedures included in Appendix G in the CPT manual and that only the single procedure code is appropriately reported when furnishing the service. Thus, for these codes the work RVUs include the work associated with moderate sedation and the direct PE include the inputs associated with typical moderate sedation.

CMS notes that studies indicate that practice patterns for endoscopic procedures are changing and that anesthesia is increasingly being reported separately for these procedures. In addition, CMS analysis of Medicare data supports this finding. To address this change in practice, CMS is considering establishing a uniform approach to valuation for all Appendix G services for which moderate sedation is no longer inherent, rather than addressing this issue at the procedure level as individual procedures are revalued.

CMS seeks public comment on approaches to address the appropriate valuation of these services:

- How to pay accurately when moderate sedation is furnished but avoid potential duplicative payments when separate anesthesia is furnished and billed separately and
- If the services in appendix G values are adjusted to no longer include moderate sedation, how should moderate sedation be reported and valued, and how to remove from the existing RVUs for these codes the inputs related to moderate sedation.

CMS notes they do not anticipate changing the approach of including moderate sedation as an inherent part of the services in Appendix G codes until they develop a policy. Thus, they do not expect to change either the evaluation of the existing RVUs for the upper GI procedures RVUs established in the CY 2014 PFS final rule and or the anticipated values in CY 2015 for the lower GI procedures.

C. Malpractice Relative Value Units (MP RVUs)

For CY 2015, CMS proposes to implement the third comprehensive review and update of MP RVUs. The proposed MP RVUs were calculated by a CMS contractor based on updated MP premium data obtained from state insurance filings. CMS says the methodology used "largely parallels" the process used in the CY 2010 update. CMS adds that the proposed MP RVUs are based on three data sources: CY 2011 and CY 2012 MP premium data (the most current data available during the CMS data collection process, weighted geographically and by specialty), CY 2013 Medicare payment and utilization data, and CY 2015 proposed work RVUs and geographic practice cost indices (GPCIs).

CMS indicates that MP premium data were obtained primarily from state departments of insurance. When they did not provide data, CMS used state rate filing data from the Perr and Knight database, which derives its data from state insurance departments. CMS collected MP insurance premium data (for $1 million/$3 million, mature, claims-made policies) from all 50 states, the District of Columbia, and Puerto Rico, and attempted to collect premium data representing at least 50 percent of the medical MP premiums paid. CMS notes that rate filings were not available in American Samoa, Guam, or the Virgin Islands. CMS reports that it adjusted the premium data to reflect mandatory surcharges for patient compensation funds.

CMS notes that not all specialties had premium data in the rate filings from all states, and that for some specialties, such data were not available from the rate filings in any state. For specialties for which there was not premium data for at least 35 states, and for specialties for which there was not distinct premium data in the rate filings, CMS crosswalked the specialty to a "similar specialty, conceptually or by available premium data," for which CMS did have sufficient and reliable data. In addition, CMS crosswalked three specialties for which it had data from at least 35 states—physician assistant, registered dietician and optometry—to a similar specialty type because the available data contained such extreme variations in premium amounts (for example, for

optometry, a range of $189 to $10,798). More specifically, given that the national average premium amount for these three specialties is below the national average premium amount for allergy and immunology, CMS crosswalked them to allergy and immunology, the specialty with the lowest premiums for which CMS had sufficient and reliable data.

CMS says that sufficient and reliable premium data were available for 41 specialty types (listed in Table 13 of the proposed rule). Table 12 of the proposed rule lists the 35 specialties for which CMS proposes a crosswalk to "similar" specialties. For example, the specialties of hospice and palliative care, optometry, and physical therapy, among others, would be crosswalked to allergy and immunology, the specialties of certified nurse midwife and gynecological/oncology would be crosswalked to obstetrics gynecology, and the specialties of nurse practitioner and certified clinical nurse specialist would be crosswalked to general practice. In addition, the specialty of certified registered nurse anesthetist would be crosswalked to anesthesiology, maxillofacial surgery to plastic and reconstructive surgery, surgical oncology to general surgery, and interventional radiology to diagnostic radiology.

CMS describes the steps for calculating the proposed MP RVUs to include the following: (1) compute a preliminary national average premium for each specialty; (2) determine which premium class(es) to use within each specialty; (3) calculate a risk factor for each specialty; (4) calculate malpractice RVUs for each HCPCS code; and (5) rescale for budget neutrality so that the total proposed resource-based MP RVUs equal the total current resource-based MP RVUs.

With respect to step #2, CMS notes that some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. To account for the presence of different classes in the MP premium data, CMS employed the following methods for calculating average premiums by specialty:

- For 13 of 41 specialties, CMS determined that there was sufficient data for surgery and nonsurgery premiums, as well as sufficient differences in rates between them, and calculated national average surgical and nonsurgical premiums.
- For 9 surgical specialties, nonsurgical premiums were rare and CMS calculated only a surgical premium.
- For 7 specialty types, MP rate filings did not include surgery or nonsurgery classes and CMS selected the unspecified premium data to calculate the national average premium amount.
- For the 12 remaining specialties, CMS blended all available premium data to develop a weighted average "blended" premium, based on the percentage of work RVUs correlated with the premium classes within each specialty (for example, the surgical premiums for a given specialty were weighted by that specialty's work RVUs for surgical services).

Table 13 of the proposed rule indicates which method applies to which Medicare specialty codes.

In the case of neurosurgery, CMS notes that premium data were available from only 24 states (not the minimum number of 35) and hence CMS proposes to blend the neurosurgery data with the surgical premium data for neurology instead of crosswalking directly to neurology or directly to another surgical specialty. CMS adds that the surgical premium for neurosurgery (presumably based on data from the 24 states) is $123,400, and argues that this amount is "similar" to the national average surgical premium amount for neurology ($96,970).

In the case of step #3 in the MP RVU methodology, CMS says that the risk factors for specialties are an index calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which CMS has sufficient and reliable data, allergy and immunology. For specialties with sufficient surgical and nonsurgical premium data, CMS calculated both a surgical and nonsurgical risk factor. For specialties with rate filings that distinguished surgical premiums with obstetrics from those without, CMS calculated a separate surgical with obstetrics risk factor. Because updated premium data are not available for suppliers of technical component (TC)-only services, such as independent diagnostic testing facilities (IDTFs), CMS updated data obtained from a 2009 survey conducted by the Radiology Business Management Association by the change in non-surgical premiums for all specialty types since the previous MP RVU update and calculated an updated TC specialty risk factor. Table 14 of the proposed rule lists the resulting surgical and/or nonsurgical risk factors for each specialty type (note, for example, that the highest surgical risk factor, 13.04, would apply to both neurology and neurosurgery). CMS notes that it continues to classify invasive cardiology services (cardiac catherizations and angioplasties) as surgery for purposes of assigning specialty-specific risk factors, and also proposes to do the same for injection procedures used in conjunction with cardiac catheterization. Table 15 of the proposed rule lists the 75 services outside of the surgical HCPCS code range that CMS proposes to consider to be surgery.

With respect to step #4, a specialty-weighted service-specific risk factor, which reflects the weighted malpractice costs across all specialties furnishing a service, was multiplied by the greater of the work RVU or PE clinical labor index for that service to reflect differences in the complexity and risk-of-service between services. For about 2,000 "low volume" services (those with less than 100 allowed services), CMS used only the risk factor of the dominant specialty providing each of these services based on 2013 Medicare claims data.

The proposed resource-based MP RVUs resulting from the five-step methodology are shown in Addendum B. CMS notes that it will make a final budget neutrality adjustment (step #5) in the final rule on the basis of the latest available 2013 utilization data but does not believe the final values will change significantly from those listed in Addendum B.

In the regulatory impact analysis, CMS notes that the updated MP RVUs have negative effects on the specialties of ophthalmology and optometry, producing 2 and 1 percent

payment reductions, respectively. However, CMS says this is due, at least in part, to its discovery of an error in calculating MP RVUs for ophthalmology codes in the last five-year review of MP RVUs, which resulted in higher MP RVUs for ophthalmology and optometry for CY 2010 than would have been the case had these RVUs been calculated correctly.

CMS says that, on average, work represents about 50.9 percent of payment for a service under the PFS, PE about 44.8 percent, and MP about 4.3 percent. For additional information on the proposed methodology for updating the MP RVUs, CMS refers readers to its contractor's report, "Report on the CY 2015 Update of the Malpractice RVUs," available under the supporting documents section of the CY 2015 PFS proposed rule.

Although CMS believes that payment rates for anesthesia should reflect relative MP resource costs, including updates to reflect changes over time, it is not proposing to update the MP RVUs for anesthesia services at this time because it believes it would be helpful to receive input from stakeholders on how it could address certain challenges (for example, the fact that anesthesia services do not have work RVUs but work RVUs are integral to the MP RVU methodology) and develop a proposal to update MP resource costs for anesthesia through future rulemaking. CMS adds that it intends to include such a proposal in the CY 2016 PFS proposed rule. CMS gives as one possible approach to calculate imputed work RVUs and MP RVUs for the anesthesia fee schedule services using the work, PE, and MP shares of the anesthesia conversion factor. ***CMS requests public comments on this approach, as well as comments on alternatives for updating anesthesia MP RVUs.***

D. Geographic Practice Cost Indices (GPCIs)

CMS notes that it completed a review and finalized updated GPCIs in the CY 2014 PFS final rule, phased in ½ of the latest GPCI adjustment in CY 2014, and also revised the cost share weights that correspond to the work, PE and MP GPCIs. CMS further notes that section 102 of the PAMA extended the 1.0 work GPCI floor through March 31, 2015. CMS refers readers to Appendix E for the CY 2015 GPCIs (which reflect the 1.0 work GPCI floor, as well as the 1.5 work GPCI floor for Alaska required by section 1848(e)(1)(G) and the 1.0 PE GPCI floor for frontier states required by section 1848(e)(1)(I)).

CMS now proposes to change the work and PE GPCI values for the Virgin Islands payment locality, for which CMS has historically set the three GPCI values at 1.0 (prior to any budget neutrality adjustment) given the absence of county level wage and rent data and the insufficient MP premium data by specialty type. More specifically, CMS proposes to use aggregate Bureau of Labor Statistics Occupational Employment Statistics (BLS OES) wage data to calculate the work GPCI and the employee wage component of the PE GPCI for the Virgin Islands payment locality, beginning for CY 2015. Since the U.S. Census Bureau American Community Survey (ACS) is not conducted in the Virgin Islands, CMS assigned a value of 1.0 for the rent index of the

PE GPCI. Since CMS has not been able to obtain MP premium data for the Virgin Islands, the existing CY 2015 MP GPCI would not change. Under the CMS proposal, for the first three months of CY 2015 (the period when the 1.0 work GPCI floor is mandated), the existing CY 2015 work GPCI value would remain 1.000 but the existing CY 2015 PE GPCI (which reflects a budget neutrality adjustment) would fall from 1.0005 to 0.960 (-4.48 percent). Similarly, for the period 4/1/2015 through 12/31/2015 (when the 1.0 work GPCI floor would not apply under current law), the existing CY 2015 work GPCI would fall from 0.998 to 0.975 (-2.30 percent) and the existing CY 2015 PE GPCI would change as noted above for the first quarter of CY 2015. For additional information regarding this proposal, CMS refers readers to its contractor's report, "Revised Final Report on the CY 2014 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available under the supporting documents section of this proposed rule.

E. Medicare Telehealth Services

CMS received several requests in CY 2013 to add various services as Medicare telehealth services effective for CY 2015. CMS proposes to add the following seven CPT and HCPCS codes because it believes they are sufficiently similar to services currently on the telehealth services list (this is known as qualifying on a category 1 basis):

- 90845 (Psychoanalysis);
- 90846 (family psychotherapy (without the patient present));
- 90847 (family psychotherapy (conjoint psychotherapy) (with patient present));
- 99354 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour);
- 99355 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes);
- G0438 (initial annual wellness visit); and
- G0439 (subsequent annual wellness visit).

On the other hand, CMS is <u>not</u> proposing to add the following services for the reasons noted:

- Fundus photography code 92250, electrocardiogram code 93010, echocardiography codes 93307 and 93308, and Doppler echocardiography codes 93308, 93320, 93321, and 93325 (by definition, the TC portion of these services needs to be furnished in the same location as the patient and thus cannot be furnished via telehealth, and the PC portion of these services are considered physicians' services and it is not necessary to include the PC of these services on the telehealth list for them to be covered when furnished remotely);
- Psychological and neuropsychological testing codes 96103 and 96120 (these services involve testing by computer, can be furnished remotely without the patient being present, and are currently payable in the same way as other physicians' services);
- A variety of codes not separately payable by Medicare, even when not furnished remotely (90887, 99090, 99091, 99358, 99359);

- Psychological testing and neuropsychological testing codes 96101, 96102, 96118, and 96119 (these services are not similar to services currently on the telehealth list and the requestor did not submit evidence supporting the clinical benefit of furnishing these services remotely, known as qualifying on a category 2 basis);
- Colposcopy codes 57452, 57454, and 57460 (same rationale as immediately above);
- HCPCS code M0064, brief office visit for the sole purposes of monitoring or changing drug prescriptions used in the treatment of mental psychoneurotic and personality disorders (this code is being deleted for CY 2015 because Medicare no longer has a need to distinguish services subject to the mental health limitation, which limited payment amounts for certain mental health services, from those not subject to the limitation, which was completely eliminated effective January 1, 2014); and
- Unspecified dermatology services related to urgent dermatologic problems and wound care (the American Telehealth Association (ATA) cited several studies to support adding dermatology services to the telehealth list but did not identify specific codes; CMS notes that some of the services that ATA had in mind may be billed under the telehealth office visit codes or the telehealth consultation G-codes).

CMS also proposes to revise §410.78(b) by deleting the list of individual services for which Medicare payment can be made when furnished via telehealth because the list has grown quite lengthy. Instead §410.78(f) would be revised to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS website (at www.cms.gov/telehealth).

CMS estimates no significant impact on PFS expenditures from the proposed additions to the list of telehealth services.

F. Valuing New, Revised and Potentially Misvalued Codes

In the CY 2012 rulemaking process, CMS proposed and finalized consolidation of the five-year review and the potentially misvalued code activities into an annual review of potentially misvalued codes. Under this process, CMS issues interim final RVUs for all revaluations and new codes in the PFS final rule with comment period and payments are based on those values during the CY covered by the final rule. CMS considers it appropriate to establish interim values for new, revised and potentially misvalued codes because of the timing incongruities between the PFS rulemaking cycle and the release of codes by the AMA CPT Editorial Panel and the RUC review process.

CMS notes that their recent revaluation of the four epidural injection codes (discussed in Section IB) provides an example of the concerns that stakeholders have raised with the existing process. CMS acknowledges that stakeholders who have experienced reductions in payments have raised several concerns with the current process of interim final valuations. In response to concerns that they did not receive notice of the possible

reductions before they occurred, CMS notes that stakeholders should be aware of changes because either CPT has made changes or CMS has identified the codes as potentially misvalued, and representatives of the affected specialties are participating in the RUC meetings. Commenters have also asserted they are not aware of RUC recommendations, they have no opportunity to respond to RUC recommendations and not all suppliers are permitted to participate in the RUC process. Additionally, some stakeholders objected to interim final decisions because they do not have an opportunity to meaningfully comment before the values are implemented. In response to comments that the process violates section 1871(a)(2) of the Act, which prescribes the rulemaking requirements for the agency in establishing payment rates, CMS states the process to establish interim final rates is in "full accordance with the statute".

1. Alternatives to the Current Process

CMS considered three alternatives to the current approach and discusses the pros and cons associated with each option. In option 1, CMS would evaluate the RUC recommendations for all new, revised, and potentially misvalued codes, and include the proposed work and MP RVUs and direct PE inputs in the first available PFS proposed rule, consider public comments on the proposals and establish final values in the final rule. CMS notes that this option allows for a full notice and comment period. They are concerned, however, that they would need to establish G-codes with identical descriptors to the predecessors of new and revised codes and continue to use existing values for new and revised codes that would be effective as part of the annual coding changes on January 1 but do not have established values. CMS is also concerned that this delays revision of values for any misvalued code for which they did not receive a RUC recommendation in time to include a proposal in the proposed rule.

The second option would propose changes in work and MP RVUS and PE inputs in the proposed rule for codes in which CMS receives RUC recommendations in time for the proposed rule and continue to establish interim final values in the final rule for other new, revised or potentially misvalued codes. CMS notes this would allow notice and comment for some codes but the timing of the RUC recommendation would impact how a code would be handled by CMS.

The final option considered would increase CMS' efforts to make more information available about the specific issues being considered and increases transparency without changing the existing process for establishing codes. This option does not solve the concerns about the lack of opportunity to provide input before interim final values are adopted.

2. Proposal to Modify the Process

CMS proposes the following process for establishing values for new, revised, and potentially misvalued codes:

- Include proposed values for all codes for which CMS has complete RUC recommendations by January 15th of the preceding year.
    - For the CY 2016 rulemaking process, CMS would include in the proposed rule proposed values for all services for which they have a RUC recommendation by January 15, 2015.

- For codes where CMS does not receive a RUC recommendation by January 15th of a year, CMS would delay revaluing the code for one year (or until they receive the RUC recommendation for the code) and include proposed values in the following year's rule.
    - CMS notes there might be some circumstances where the RUC recommendation is received by January 15th but CMS is not able to propose values in that year's proposed rule and CMS would treat these codes as if they had not received recommendations before January 15th.
    - CMS proposes to adopt coding policies and payment rates that conform, to the extent possible, to the policies and rates in place for the previous year.
        - For codes that were revised or deleted as part of the annual CPT coding change and when the changes would affect the value of a code, CMS proposes to create G-codes to describe the predecessor codes. If CPT code revisions did not affect the resource inputs, CMS proposes to use the revised codes and continue to pay at the same rate.
        - For new codes that describe completely new services, CMS proposes to work with the RUC to ensure recommendations are received in time to include proposed values in the proposed rule. If RUC recommendations were not received in time and CMS determines it is in the public interest to use a new code, CMS proposes to establish values for the code's initial year using the current policy of considering RUC recommendations if available for the final rule and proposing interim final values. CMS also notes that when it would not be appropriate to establish interim final values, CMS would have contractors price the code for the initial year.

CMS requests comments on the following topics:

- Is this proposal preferable to the present process? Is another one of the alternatives better?
- If this proposal was implemented, should it be implemented in CY 2016 or is more time needed? What factors should CMS consider in selecting an implementation date?
- Are there alternatives other than the use of G-codes to allow CMS to address the annual CPR changes through notice and comment rather than interim final rulemaking?

3. Refinement Panel

If the proposal to modify the valuation process for new, revised and potentially misvalued codes is adopted, CMS believes that there would only be a limited number of interim final values that describe totally new services and there would no longer be a need for the refinement panel process. Thus, CMS is proposing to eliminate the refinement panel process.

G. Chronic Care Management (CCM)

In the CY 2014 PFS final rule with comment period, CMS finalized a policy to pay separately for care management services furnished to Medicare beneficiaries with two or more chronic conditions beginning in CY 2015, and adopted the following code to use for reporting this service:

- GXXX1 Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days.

CMS notes that this new code was designed to pay separately for non-face-to-face care coordination services.

CMS now proposes new policies or changes to existing policies relating to CCM adopted in the CY 2014 PFS final rule with comment period. First, CMS proposes a work RVU of 0.61 (which is the portion of the work RVU for CPT code 99495 (Transitional Care Management Services) that remains after subtracting the work attributable to the face-to-face visit required as part of 99495. Second, CMS proposes 20 minutes of clinical labor time as direct PE inputs for the CCM code. Third, CMS proposes to calculate the MP RVU for the CCM code using the weighted risk factors for the specialties that it believes will furnish this service. In terms of changes to existing policy, CMS proposes to remove the requirement that, in order to count the time spent by clinical staff providing aspects of CCM services toward the CCM time requirement, the clinical staff person must be a direct employee of the practitioner or the practitioner's practice. CMS further proposes to remove the restriction that services provided by clinical staff under general (rather than direct) supervision may be counted only if they are provided outside of the practice's normal business hours. CMS also proposes to adopt equivalent, revised policies for the Transitional Care Management (TCM) services (while still requiring direct supervision for the evaluation and management service that is a required element of TCM).

In the CY 2014 PFS final rule with comment period, CMS announced its intention to adopt standards for CCM services. In this proposed rule, CMS says that it consistently found that many of the standards it thought were important overlapped in significant ways with the scope of service or with the billing requirements for the CCM services that had been finalized in the CY 2014 final rule, or with other Medicare requirements or

other federal requirements that apply generally to health care practitioners. Thus, CMS has decided not to propose an additional set of standards and instead to emphasize that certain requirements are inherent in the elements of the existing scope of service for CCM services (see below), and clarify that these must be met in order to bill for CCM services.

CMS does propose a new scope of service requirement, that CCM services must be furnished with the use of an electronic health record (EHR) or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers within the practice, including those furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice. CMS adds that the practitioner must use EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170 (for CY 2015, this would be an EHR certified to at least the 2014 Edition certification criteria). At a minimum, this means that the practice must use EHR technology that meets the certification criteria adopted at 45 CFR 170.314(a)(3), (a)(4), (a)(5), (a)(6), (a)(7), and (e)(2) pertaining to the capture of demographics, problem lists, medications, and other key elements related to the ultimate creation of an electronic summary care record.

CMS requests comment on any changes to the scope of service or billing requirements for CCM services that may be necessary to ensure that the practitioners who bill for these services have the capability to furnish them and that CMS can appropriately monitor billing for these services. CMS asks that commenters provide as much specific detail as possible regarding additional scope of service elements or beneficiary safeguards that may be necessary and how they can be applied to the broad complement of practitioners who may furnish CCM services.

CMS reminds readers that the scope of the CCM service includes the following (somewhat abbreviated for purposes of this summary):

- Access to care management services 24-hours-a-day, 7-days-a-week;
- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments;
- Care management for chronic conditions including systematic assessment of patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications;
- Creation of a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and value;
- Management of care transitions between and among health care providers and settings, including referrals to other clinicians, follow-up after a beneficiary visit to an emergency department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities;

- Coordination with home and community-based clinical service providers; and
- Enhanced opportunities for a beneficiary and any relevant caregiver to communicate with the practitioner, not only via telephone, but also via secure messaging, internet or other asynchronous non-face-to-face consultation methods.

CMS also reminds readers that the billing requirements for CCM services require the practitioner to:

- Inform the beneficiary about the availability of the CCM services from the practitioner and obtain his or her written agreement to have the services provided, including the beneficiary's authorization for the electronic communication of the patient's medical information with other treating providers;
- Document that all of the CCM services were explained and offered to the patient, and note the beneficiary's decision to accept or decline these services;
- Provide the beneficiary a written or electronic copy of the care plan and document in the EHR that the care plan was provided;
- Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of a 30-day period) and the effect of a revocation of the agreement on CCM services; and
- Inform the beneficiary that only one practitioner can furnish and be paid for these services during the 30-day period.

Finally, CMS proposes that practitioners participating in the Multi-payer Advanced Primary Care Practice Demonstration or the Comprehensive Primary Care Initiative not be allowed to bill Medicare for CCM services for any beneficiary attributed to the practice for purposes of participating in either of these initiatives (since CMS views this as duplicative payment). However, they could bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed to the practice under either of these initiatives. ***CMS solicits comments on the extent to which CCM services may not actually be duplicative (in the first instance) and, if so, how Medicare's reimbursement policy could be tailored to address those situations.***

H. Definition of Colorectal Cancer Screening Tests

In light of a recent study in the *Journal of the American Medical Association* indicating an increase in the percentage of colonoscopies and upper endoscopy procedures furnished using an anesthesia professional, CMS proposes to revise the definition of "colorectal cancer screening tests" at §410.37(a)(1) to include anesthesia that is separately furnished in conjunction with screening colonoscopies. This will have the effect of relieving beneficiaries of cost-sharing obligations (both coinsurance and deductible) for such anesthesia services. CMS notes that an analysis of 2013 Medicare claims data found that in 53 percent of screening colonoscopies a separate anesthesia claim was reported. CMS adds that if the proposed policy is finalized, it will be necessary to establish a modifier for reporting the relevant anesthesia codes. CMS says it will provide appropriate and timely information on this new modifier and its proper use to facilitate correct billing of the services.

I. Payment of Secondary Interpretation of Images

CMS says that questions have arisen as to whether and under what circumstances it would be appropriate for Medicare to permit payments under the PFS when physicians furnish subsequent interpretations of existing radiology images. Under current policy, Medicare can pay for a second interpretation (which is billed using modifier -77) under "unusual circumstances (for which documentation is provided)." ***CMS seeks comment to assess whether there is an expanded set of circumstances under which it would be appropriate to allow more routine Medicare payment for a second professional component for radiology services, and whether such a policy would be likely to reduce the incidence of duplicative advanced imaging studies.***

More specifically, ***CMS seeks comment on the following questions***:

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

CMS adds that it welcomes input on any additional considerations, and says that upon reviewing the comments received, it will consider whether any further action is appropriate, such as proposing under future rulemaking to allow for payment of subsequent interpretations of advanced diagnostic images in lieu of duplicative studies.

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

CMS proposes changes to regulatory language at §§410.59(c), 410.60(c), and 410.62(c) to clarify the practice types for qualified occupational therapists, physical therapists, and speech-language pathologists (which are part of the basic qualifications of such practitioners in private practice). CMS says the changes remove unnecessary distinctions and redundancies within the regulations. For example, §410.60 would now refer to individuals who "[e]ngage in the private practice of physical therapy on a regular basis as an individual in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these."

K. Payments for Physicians and Practitioners Managing Patients on Home Dialysis

In the CY 2011 PFS final rule with comment period, CMS changed its policy relating to home dialysis monthly capitation payment (MCP) services to require the MCP physician or practitioner to furnish at least one face-to-face patient visit per month as a condition of payment but says it inadvertently did not modify its billing guidelines for home dialysis (less than a full month) to be consistent with partial month scenarios for center-based dialysis patients.

CMS now, therefore, proposes to allow the MCP physician or practitioner to bill for the age appropriate home dialysis MCP service (as described by HCPCS codes 90963 through 90966) for the home dialysis (less than a full month) scenario if the MCP physician or practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-to-face patient visit. For example, if a home dialysis patient was hospitalized during the month but at least one face-to-face outpatient visit and a complete monthly assessment were furnished, the MCP physician or practitioner should bill for the full home dialysis MCP service.

III. Other Provisions of the Proposed Regulations

A. Ambulance Extender Provisions

In light of Congressional actions taken under the Pathway for SGR Reform Act of 2013 and PAMA, CMS extends the following special ambulance payment policies through March 31, 2015:

- A 3 percent payment increase for covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area;
- A 2 percent payment increase for covered ground ambulance transports that do not originate in previously mentioned rural areas or census tracts; and
- A 22.6 percent rural bonus for ground ambulance services where transportation originates in a qualified rural area (those comprising the lowest 25th percentile of all rural populations arrayed by population density and include Goldsmith areas,

a type of rural census tract). This is sometimes referred to as the “Super Rural Bonus” and the qualified areas as “super rural” areas.

CMS considers the relevant statutory provisions to be self-implementing.

B. Proposed Changes in Geographic Area Delineations for Ambulance Payment

CMS notes that on February 28, 2013, the Office of Management and Budget (OMB) issued OMB Bulletin No. 13-01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of these delineations (a copy is available at http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf). CMS proposes to implement the new OMB delineations beginning in CY 2015 to more accurately identify urban and rural areas for ambulance fee schedule payment purposes.

Beginning in CY 2015, CMS also proposes to adopt the most recent modifications of the Rural-Urban Commuting Area (RUCA) codes, which use urbanization, population density, and daily commuting data to categorize every census tract in the country. More specifically, the agency proposes to designate as rural areas (for ambulance payment purposes) (1) those census tracts that fall at or above RUCA level 4.0. and (2) those census tracts that fall within RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. CMS notes that this would mean that many counties that are designated as urban at the county level based on population would have rural census tracts within them.

CMS says that adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. However, under the proposed rule, 122 ZIP codes would change from rural to urban and 100 ZIP codes would change from urban to rural, meaning that ambulance providers and suppliers in those areas may experience payment decreases or increases, respectively. CMS notes that West Virginia would have the most ZIP codes changing from rural to urban, while Ohio would have the most ZIP codes changing from urban to rural. Table 17 of the proposed rule provides a state-by-state assessment of the impact of the revised OMB delineations and updated RUCA codes.

CMS estimates that the adoption of the revised OMB delineations and the updated RUCA codes would have minimal fiscal impact on the Medicare program because payments would, in effect, be redistributed.

C. Clinical Laboratory Fee Schedule

CMS acknowledges that section 216 of PAMA requires the agency to implement a new Medicare payment system for clinical diagnostic laboratory tests based on private payer rates and also rescinds prior authority for adjustments based on technological changes for tests furnished on or after April 1, 2014. Thus, CMS is not proposing any revisions to payment amounts based on technological changes and says it will instead establish through rulemaking the parameters for the collection of private payer rate information and other requirements to implement section 216 of the PAMA.

D. Removal of Employment Requirements for Services Furnished "Incident to" Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Visits

To provide RHCs and FQHCs with as much flexibility as possible to meet their staffing needs, CMS proposes to revise existing regulations (in several places) to remove the requirement that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC to allow nurses, medical assistants, and other auxiliary personnel to furnish "incident to" services under contract in RHCs and FQHCs.

CMS says this proposal would involve no cost to the federal government, and adds that it cannot estimate a cost savings for RHCs and FQHCs.

E. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models

CMS notes that it will be conducting qualitative and quantitative analyses of the impact of models conducted under section 1115A of the Social Security Act on quality of care, program expenditures and other factors. To do this, CMS says it must be able to determine specifically which individuals are receiving services from or are subject of the intervention being tested by the entity participating in the model test and, therefore, must have access to patient records not generally available to the agency.

CMS proposes to exercise its authority in section 1115A(b)(4)(B) to establish requirements for states and other entities participating in the testing of past, present, and future models under section 1115A to collect and report information that CMS has determined is necessary to monitor and evaluate such models. This means that model participants, and providers and suppliers working under the models operated by such participants, would be required to produce such individually identifiable health information and such other information as the Secretary identifies as being necessary. CMS further proposes to require the submission of identifiable health and utilization information for patients of private payers treated by providers/suppliers participating in the testing of a model under section 1115A of the Act when an explicit purpose of the model test is to engage private sector payers. CMS adds that if finalized, this regulation will provide clear legal authority for HIPAA covered entities to disclose any required protected health information, which is intended to be the minimum data necessary to carry out statutorily mandated research work relating to model impact.

The proposed rule gives a lengthy (but not necessarily comprehensive) list of examples of the types of information that may be required, including the following: beneficiary, patient, participant, and family socio-demographic and ethnic characteristics; care management details, such as details regarding the provision of services, payments or goods to beneficiaries, patients, participants, families, or other providers; and beneficiary, patient, and participant health behaviors.

CMS does not anticipate an impact from this proposal, noting that participants in Innovation Center models generally receive funding support.

F. Local Coverage Determination Process for Clinical Diagnostic Testing

Section 1834A(g) of the Social Security Act, as added by section 216 of PAMA, states: "A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1869(f)(2)(B)), including the appeals and review process for local coverage determinations [LCDs] under part 426 of title 42, Code of Federal Regulations (or successor regulations)."

In response, CMS proposes an expedited LCD process for clinical diagnostic laboratory testing that differs from the current LCD process used for other services. This new process would only apply to all new draft clinical diagnostic laboratory test LCDs published on or after January 1, 2015. CMS argues that a process that ensures transparency and stakeholder participation can be achieved without utilizing the current LCD process in its entirety. CMS adds that following all steps of the current LCD process could mean that LCDs would not be finalized quickly enough for even a fraction of the thousands of new clinical diagnostic tests developed each year, particularly molecular tests. CMS also notes that the LCD manual was originally written about 25 years ago. In developing its proposed expedited LCD process, CMS says it took into account experience under a pilot project that the agency launched with Palmetto GBA that has been focusing on molecular diagnostic (genetic) laboratory tests. In particular, CMS points out that Palmetto wrote a single molecular diagnostic laboratory testing LCD that outlined the framework they would follow in determining coverage of all molecular diagnostic tests in their jurisdiction, and that LCD included a list of covered molecular diagnostic tests.

Table 18 of the proposed rule (reproduced below) compares the current and proposed LCD processes.

Table 18: Comparison of Current LCD Process versus Proposed LCD Process for Clinical Diagnostic Laboratory Tests

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

With respect to the proposed process, CMS says it would expect the draft LCDs to "outline the criteria the MAC [Medicare Administrative Contractor] would use when determining whether a specific clinical diagnostic laboratory test or a group of tests are covered or non-covered." Also, the MAC would have the discretion to take draft LCDs to the Carrier Advisory Committee (CAC) where the MAC determines that a CAC meeting would contribute to the quality of the final policy. In the event the MAC involves the CAC, CMS would require the public comment period be extended to allow for the CAC to be held before the final policy is issued.

CMS notes that (consistent with Chapter 13, section 13.7.3 of the Medicare Program Integrity Manual) the proposed new process would not apply to clinical diagnostic laboratory testing LCDs that are being revised for the following reasons: to liberalize an existing LCD; being issued for a compelling reason; making a non-substantive correction; providing a clarification; making a non-discretionary coverage or diagnostic coding update; making a discretionary diagnosis coding update that does not restrict; or revising to effectuate an Administrative Law Judge's decision on a Benefits Improvement and Protection Act (BIPA) 522 challenge. The process would also not apply to the NCD process or "other vehicles of coverage including claim-by-claim adjudication."

G. Private Contracting/Opt-out

Certain physicians and practitioners may opt-out of Medicare if certain conditions are met and furnish through private contracts with Medicare beneficiaries services that would otherwise be covered by Medicare. CMS proposes that a determination relating

to the status of opt-out or private contracts would be appealable under the enrollment appeals process currently available for providers and suppliers in part 498. CMS further proposes that a determination that Medicare payment cannot be made to a beneficiary for services furnished by a physician or practitioner who has opted out of Medicare would be appealable under the existing claims appeals procedures in part 405, subpart I. CMS proposes regulatory changes in several places to accomplish this.

CMS also proposes technical changes to the private contracting regulations to correct a cross-reference relating to the definition of "emergency care services" and to replace references to Medicare+Choice with the term "Medicare Advantage."

H. Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

Section 1842(b)(6)(D) of the Social Security Act generally allows for two types of substitute physician billing arrangements: (1) an informal reciprocal arrangement where doctor A substitutes for doctor B on an occasional basis and doctor B substitutes for doctor A on an occasional basis; and (2) an arrangement where the services of the substitute physician are paid for on a per diem basis or according to the amount of time worked. Substitute physicians in the second type of arrangement are sometimes referred to as "locum tenens" physicians. CMS indicates it has heard anecdotally that locum tenens physicians are being used to fill staffing needs or, on a temporary basis, to replace physicians who have permanently left a medical group or employer, and is concerned about the resulting operational and program integrity issues, especially where these practices involve continued use of a departed physician's National Provider Identifier (NPI), even without the departed physician's knowledge. In addition, a substitute physician's NPI is not currently captured on CMS claim forms.

CMS solicits comments on the policy for substitute physician billing arrangements for possible use in future rulemaking, and specifically seeks input on the following:

1. How physicians and other entities are currently utilizing the services of substitute physicians and billing for them.
2. When a regular physician is considered "unavailable" for purposes of utilizing a substitute.
3. Whether CMS should limit substitute physician billing arrangements to those "between the two physicians" (rather than between a medical group, employer or other entity and the substitute physician).
4. Whether CMS should permit the sequential use of multiple substitute physicians provided that each substitute furnishes services for the unavailable physician for no more than 60 continuous days.
5. Whether CMS should treat reciprocal substitute physician billing arrangements differently than paid (or locum tenens) arrangements.
6. Whether substitute physicians furnishing services to Medicare beneficiaries should be required to enroll in the Medicare program.

7. Whether entities submitting claims for services furnished by substitute physicians should include the identity of the substitute physician on the claim form (which would need to be modified to accommodate this).
8. Whether CMS should place limitations on the use of the substitute physician and billing for his or her services (for example, a requirement that the departing physician be a party to the substitute physician billing arrangement), and whether such limitations should be different depending on the circumstances underlying or requiring the use of the substitute.
9. Whether CMS should limit or prohibit the use of substitute physician billing arrangements in certain programs or for certain purposes (for example, the Medicare Shared Savings Program).
10. The impact of substitute physician billing arrangements on CMS programs that rely on the Provider Enrollment, Chain and Ownership System, enforcement of the physician self-referral law, and program integrity oversight.
11. Additional program integrity safeguards that should be included to protect against program and patient abuse.
12. Any other relevant issues that CMS should consider.

I. Reports of Payments or Other Transfers of Value to Covered Recipients

Current law relating to the Open Payments (Sunshine Act) program requires applicable drug and device manufacturers and group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on certain payments or transfers of value made to physicians and teaching hospitals. Implementing regulations are found at 42 CFR Part 402, subpart A, and Part 403, subpart I. More importantly for purposes of the proposed rule, §403.904(g)(1) excludes the reporting of payments associated with certain continuing education events (those meeting the accreditation or certification requirements and standards of certain listed organizations), and §403.904(c)(8) requires reporting of the marketed name for drugs and biologicals but makes reporting the marketed name of devices or medical supplies optional.

CMS proposes to eliminate the current exclusion for certain continuing education events because this has had the unintended consequence of appearing to endorse or support the continuing education events of some accrediting organizations but not others. However, CMS notes that when an applicable manufacturer or GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under §403.904(i)(1). On the other hand, when an applicable manufacturer or GPO conditions its financial sponsorship on the participation of particular covered recipients, or pays a covered recipient directly for speaking at such an event, those payments would be subject to disclosure. CMS notes that it considered two alternatives, expanding the list of accrediting organizations for which an exclusion would apply or articulating accreditation or certification standards that would allow a continuing education program

to qualify for an exclusion ***and seeks comments on these alternatives, including suggestions about what standards, if any, CMS should incorporate.***

CMS further proposes to require the reporting of the marketed name for devices which are associated with a payment or transfer of value (as well as the marketed name for drugs, biologicals, or medical supplies), and says this would make the reporting requirements consistent. However, note that §403.904(c)(8)(i) says that, for drugs and biologicals, if the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on clinicaltrials.gov and no comparable policy is proposed for devices and medical supplies.

In addition, CMS proposes to require the reporting of the following distinct forms of payment: stock; stock option; or any other ownership interests (rather than continuing to permit combined reporting) in order to collect more specific data regarding the forms of payments. ***CMS requests comments on the extent to which users of the Open Payments data set find this disaggregation to be useful, and whether this change presents operational or other issues on the part of applicable manufacturers.***

CMS proposes to begin the data collection requirements affected by the above proposals on January 1, 2015.

CMS also proposes to remove the definition of a "covered device" at §403.902 because the agency believes it is duplicative of the definition of "covered drug, device, biological or medical supply."

CMS estimates that it will take 1 hour for support staff to report payments or other transfers of value to CMS which were provided to covered recipients as compensation for speaking at a continuing education program (at a labor cost of $26.39/hr), and 0.5 hours for support staff to revise an applicable manufacturer's or applicable GPO's reporting system to report the form of payment (at a labor cost of $47.55/hr). CMS does not further explain the different labor cost assumptions. In any event, copies of the supporting statement and any related forms for this and other proposed paperwork collections can be accessed at http://www.cms.hhs.gov/PaperworkReductionActof1995, or interested parties may request this information via email at Paperwork@cms.hhs.gov or by calling the Reports Clearance Office at 410-786-1326.

J. Physician Compare Website

CMS reviews previously finalized policies for public reporting on Physician Compare and summarizes them in Table 19 of the proposed rule (reproduced below)

TABLE 19: Summary of Previously Finalized Policies for Public Reporting on Physician Compare

Data Collection Year	Public Reporting Year	Reporting Mechanism(s)	Quality Measures and Data for Public Reporting
2012	2013	Web Interface (WI), EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and PQRS GPRO, successful e-prescribers under eRx, and participants in EHR for groups and individuals as applicable.
2012	2014	WI	5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices with a minimum sample size of 25 patients and Shared Savings Program ACOs.
2013	2014	WI, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and PQRS GPRO, successful e-prescribers under eRx, and participants in EHR, as well as for EPs who earn a Maintenance of Certification (MOC) Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2013	Expected to be December 2014	WI	Up to 6 DM and 2 CAD measures collected via the WI for groups of 25 or more EPs with a minimum sample size of 20 patients. Will include composites for DM and CAD, if feasible.
2013	Expected to be December	WI	5 CG-CAHPS summary measures for groups of 100 or more EPs reporting via the WI and 6 ACO CAHPS summary measures for Shared Savings Program ACOs.
2014	Expected to be 2015	WI, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and PQRS GPRO, participants in EHR, as well as for EPs who earn a Maintenance of Certification (MOC) Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2014	Expected to be late 2015	WI, EHR, Registry	All measures reported via the GPRO WI, 13 EHR, and 16 Registry GPRO measures are also available for group practices of 2 or more EPs and Shared Savings Program ACOs with a minimum sample size of 20 patients. Include composites for DM and CAD, if feasible.
2014	Expected to be late 2015	WI, Certified Survey Vendor	Up to 12 CG-CAHPS summary measures for groups of 100 or more EPs reporting via the WI and group practices of 25 to 99 EPs reporting via a CMS-approved certified survey vendor, as well as 6 ACO CAHPS summary measures for Shared Savings Program ACOs reporting through the GPRO web interface or other CMS-approved tool or interface.
2014	Expected to be late 2015	Registry, EHR, or Claims	A sub-set of 20 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI that are collected through a Registry, EHR, or claims with a minimum sample size of 20 patients.

Data Collection Year	Public Reporting Year	Reporting Mechanism(s)	Quality Measures and Data for Public Reporting
2014	Expected to be late 2015	Registry, EHR, or Claims	Measures from the Cardiovascular Prevention measures group reported by individual EPs in support of the Million Hearts Initiative with a minimum sample size of 20 patients.

CMS then reviews proposals for public data disclosure on Physician Compare in 2015 and 2016, and summarizes these in Table 20 of the proposed rule (reproduced below).

TABLE 20: Summary of Proposed Data for Public Reporting

Data Collection Year	Publication Year	Data Type	Reporting Mechanism	Proposed Quality Measures and Data for Public Reporting
2013	2015	PQRS	Registry, EHR, or Claims	Twenty 2013 PQRS individual measures collected through a Registry, EHR, or claims mirroring the measures finalized for 2014 (78 FR 74454).
2015	2016	Multiple	Web Interface, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and PQRS GPRO, participants in EHR, and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2015	2016	PQRS GPRO & ACO GPRO	Web Interface, EHR, & Registry	All 2015 PQRS GPRO measures reported via the Web Interface, EHR, and Registry are available for public reporting for group practices of 2 or more EPs and all measures reported by ACOs with a minimum sample size of 20 patients.
2015	2016	CAHPS for PQRS& CAHPS for ACOs	CMS-Specified Certified CAHPS Vendor	2015 CAHPS for PQRS for groups of 2 or more EPs and CAHPS for ACOs for those who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2015	2016	PQRS	Registry, EHR, or Claims	All 2015 PQRS measures for individual EPs collected through a Registry, EHR, or claims.
2015	2016	QCDR data	QCDR	All 2015 QCDR data available for public report on Physician Compare at the individual level or aggregated to a higher level of the QCDR's choosing.

With respect to its public reporting intentions, CMS defines "technically feasible" to mean that there are no operational constraints inhibiting the agency from moving forward on a given public reporting objective, such as delays and/or issues related to data collection which render a set of quality data unavailable in the timeframe necessary for public reporting. And CMS defines "statistically comparable," to mean that the quality measures are analyzed and proven to measure the same phenomena in the same way regardless of the mechanism through which they were collected.

In the context of its proposed data for public reporting in 2015 and 2016, CMS proposes to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file. However, CMS proposes that not all such measures would necessarily be included on the Physician Compare profile pages. This is because consumer testing has shown that including too much information and/or measures that are not well understood by consumers on these pages can negatively impact a consumer's ability to make informed decisions. CMS says that its analysis of the measure data once collected, consumer testing, and stakeholder feedback would determine which measures are published on the Physician Compare profile pages.

CMS requests comment on creating composites using 2015 data and publishing composite scores in 2016 by grouping measures based on the PQRS Group Practice Reporting Option (GPRO) measure groups, if technically feasible. CMS gives the following examples of possible composites: care coordination/patient safety measures; coronary artery disease module; diabetes mellitus module; and preventive care measures. ***CMS also requests comment on creating composites and publishing composite scores in the case of individual practitioners***, and offers the following examples of potential composites: coronary artery disease; diabetes mellitus; general surgery; oncology; preventive care; rheumatoid arthritis; and total knee replacement.

For purposes of reporting both group and individual practitioner performance data, CMS proposes to calculate benchmarks, starting with the 30th percentile (corresponding to the minimum attainment level) and ending with the 90th percentile (corresponding to the maximum attainment level). As noted in Table 20, CMS is also proposing to accelerate the availability of performance data for individual eligible professionals by publicly reporting, in early 2015, 2013 PQRS data for 20 PQRS measures collected via registry, EHR and claims.

CMS notes that it previously indicated an interest in including specialty society measures on Physician Compare and ***now seeks comment on posting these measures on the website as well as on the option of linking from Physician Compare to specialty society websites that publish non-PQRS measures***. CMS adds that it is working to identify possible societies to reach out to, and seek comment on the concept, as well as potential specific society measures of interest.

With respect to public disclosure of qualified clinical data registry (QCDR) data, CMS says that a QCDR would be required to declare during its self-nomination if it plans to post data on its own website and allow Physician Compare to link to it or if it will provide data to CMS for public reporting on Physician Compare. CMS also proposes that measures collected via QCDRs must meet the established public reporting criteria, including a 20 patient minimum sample size.

K. Physician Payment, Efficiency, and Quality Improvement – Physician Quality Reporting System

The proposed rule primarily focuses on CMS proposals related to the 2017 Physician Quality Reporting System (PQRS) payment adjustment, which will be based on an eligible professional's or a group practice's reporting of quality measures data during the 12-month calendar year reporting period occurring in 2015 (that is, January 1 through December 31, 2015). The PQRS payment adjustment for 2016 and subsequent years for failure to meet the PQRS reporting requirements for the applicable reporting period is -2 percent (that is, payment for services paid under the PFS is made at 98.0 percent, which is the applicable percent for those years).

1. Requirements for the PQRS Reporting Mechanisms

CMS is not proposing to make changes to the claims-based reporting mechanism.

For the qualified registry reporting mechanism, CMS proposes to require a qualified registry to be able to collect needed data elements and transmit to CMS the data at the Tax Identification Number (TIN)/National Provider Identifier (NPI) level for **all** 18 cross-cutting measures specified in Table 21 of the proposed rule for which the registry's participating eligible professionals (EPs) are able to report.[2] This is because CMS is proposing to require that an EP or group practice who sees at least 1 Medicare patient in a face-to-face encounter to report on at least 2 cross-cutting PQRS measures (in addition to meeting other reporting requirements). CMS says it is proposing to require the ability to report all cross-cutting measures of relevance to a qualified registry's participating EPs because this would give these EPs the flexibility to choose which 2 cross-cutting measures they wish to report. For the qualified registry reporting mechanism, CMS is also proposing to push back the reporting deadline from the last Friday of February following the applicable reporting period to March 31 (for example, March 31, 2016 for the reporting periods ending in 2015). ***CMS seeks comment on whether to propose in future rulemaking to allow more frequent submissions of data, such as quarterly or year-round submissions, rather than having only one opportunity to submit data as is the current process.***

[2] Examples of these cross-cutting measures include: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention; Documentation of Current Medications in the Medical Record; and Pneumonia Vaccination Status for Older Adults.

With respect to reporting via direct electronic health record (EHR) and EHR data submission vendor products that are certified electronic health record technology (CEHRT), CMS notes that updated implementation guides for data file formats for 2015, when available, will be posted at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms. These implementation guides will describe the technical requirements for data submission, which CMS proposes to continue to apply to direct EHR products and EHR data submission vendor products for 2015 and beyond. For 2015 and beyond, CMS also proposes to have the EP or group practice provide the CMS EHR Certification Number of the product used. As it does for the qualified registry reporting mechanism, ***CMS seeks comment on whether to allow more frequent submission of PQRS data in the future.***

With respect to reporting via QCDR, CMS proposes to require a QCDR to have at least 3 outcome measures (or, in lieu of 3 outcome measures, at least 2 outcome measures and at least 1 of the following other types of measures – resource use, patient experience of care, or efficiency/appropriate use). Unfortunately, the proposed rule provides only a single example of an outcome measure, unplanned hospital readmission after a procedure. In a later section of the proposed rule, CMS says that for QCDR reporting purposes for the 2017 PQRS payment adjustment, an outcome measure 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." CMS also proposes to define resource use, patient experience of care, and efficiency/appropriate use measures as follows:

- A resource use measure "is a measure that is a comparable measure of actual dollars or standardized units of resources applied to the care given to a specific population or event, such as a specific diagnosis, procedure, or type of medical encounter."
- A patient experience of care measure "is a measure of person- or family-reported experiences (outcomes) of being engaged as active members of the health care team and in collaborative partnerships with providers and provider organizations."
- An efficiency/appropriate use measure "is a measure of the appropriate use of health care services (such as diagnostics or therapeutics) based upon evidence-based guidelines of care, or for which the potential for harm exceeds the possible benefits of care."

[Editor's Note: The various definitions quoted above do not appear to cleanly differentiate between measure types and may make it difficult for QCDRs and EPs reporting via QCDRs to determine whether they will meet the proposed reporting requirements. For example, CMS appears to want to differentiate between outcome measures and patient experience of care measures for purposes of the new QCDR reporting requirements but its proposed definitions do not appear to do this.]

For QCDRs, CMS proposes to increase the maximum number of non-PQRS measures that can be reported on behalf of an EP from the current 20 to 30. CMS also provides

more guidance about what is meant by a non-PQRS measure. It not only includes a measure that is not contained in the PQRS measure set for the applicable reporting period but also includes a measure that may be in the PQRS measure set but has substantive differences in the manner it is reported by the QCDR. CMS gives as one example of the latter the Consumer Assessment of Healthcare Providers and Systems (CAHPS) reported via a QCDR because although CAHPS for PQRS is technically contained in the PQRS measure set, CMS considers the changes that will need to be made to be available for reporting by individual EPs significant enough as to treat CAHPS for PQRS as a non-PQRS measure.

Beginning in 2015, CMS is also proposing that a QCDR make available to the public the quality measures data for which its EPs report. At a minimum, the QCDR would need to report the title and description of the measures that a QCDR reports as well as the performance results for each measure the QCDR reports. CMS further proposes that the QCDR must have the quality measures data by April 31 of the year following the applicable reporting period and this data must be available on a continuous basis and be continuously updated as the measures undergo changes in measure title and description, as well as when new performance results are calculated. CMS proposes to defer to the QCDR in terms of the method it will use to publicly report the quality measures data. For example, CMS says it would be sufficient for a QCDR to publicly report performance rates of EPs through means such as, but not excluding, board or specialty websites, performance or feedback reports, or listserv dashboards or announcements. CMS adds that a QCDR would meet the proposed public reporting requirement if the QCDR's measures data were posted on Physician Compare. CMS also proposes to defer to the QCDR to determine whether to report performance results at the individual EP level or aggregate the results for certain sets of EPs who are in the same practice together.

Beginning in 2015, CMS also proposes to allow an entity that uses an external organization for purposes of data collection, calculation or transmission to meet the definition of a QCDR so long as the entity has a signed, **written** agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of January 1 of the year prior to the year for which the entity seeks to become a QCDR (for example, January 1, 2014, to be eligible to participate for purposes of data collected in 2015). This is intended to address situations where an entity is not able to meet QCDR requirements solely on its own but could do so in conjunction with another entity.

CMS also proposes that an entity that has broken off from a larger organization may be considered to be in existence for the purposes of QCDR qualification as of the earliest date the larger organization begins continual existence. CMS further proposes to extend the deadline for QCDRs to submit quality measures data calculations to CMS to March 31, and ***again asks for input regarding the possibility of more frequent submissions of data.***

With respect to the Group Practice Reporting Option (GPRO), CMS proposes an earlier deadline for registering to participate in the GPRO, June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in 2015), rather than the current September 30. This is being proposed because CMS believes there is benefit in providing timelier feedback reports. ***CMS seeks comment on whether to allow more frequent submissions of data through the GPRO Web interface.***

2. Proposed Criteria for the Satisfactory Reporting for Individual EPs for the 2017 PQRS Payment Adjustment

The proposed satisfactory reporting criteria for individual EPs for the 2017 PQRS payment adjustment are as follows:

Via Claims

> Report at least 9 measures, covering at least 3 of the National Quality Strategy (NQS) domains and report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 9 measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP must report on at least 2 measures contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the EP, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP must report on at least 2 cross-cutting measures. Measures with a 0 performance rate would not be counted.

Via Qualified Registry

> As above for claims, or report at least 1 measures group and report each measures group for at least 20 patients, a majority of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

Via EHR Direct Product or EHR Data Submission Vendor

> Report 9 measures covering at least 3 NQS domains. If an EP's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the EP must report the measures for which there is Medicare patient data. An EP must report at least 1 measure for which there is Medicare patient data.

CMS notes that EPs submitting less than 9 measures will again be subject to the measure application validity (MAV) process to allow the agency to determine whether the EP should have reported quality data codes for additional measures.

With respect to the issue of face-to-face encounters (relevant for reports via claims or qualified registry), CMS proposes to determine whether an EP had a "face-to-face" encounter by seeing whether the EP billed for services under the PFS that are associated with such encounters, such as general office visit codes, outpatient visits, and surgical procedures. CMS notes that it would not include telehealth visits as face-to-face encounters for purposes of the cross-cutting-measure reporting requirement.

3. Satisfactory Participation in a QCDR by Individual EPs

CMS proposes the following criteria for satisfactory QCDR participation for the 2017 PQRS payment adjustment:

> Report at least 9 measures available for reporting under a QCDR covering at least 3 NQS domains, and report each measure for at least 50 percent of the EP's patients. Of these measures, report on at least 3 outcome measures, or, if 3 outcome measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures – resource use, patient experience of care, or efficiency/appropriate use.

See the discussion in section III.K.1 above regarding the issue of outcome and other measures.

4. Proposed Criteria for Satisfactory Reporting for Group Practices Selected to Participate in the GPRO

CMS emphasizes that a group practice must register to participate in the PQRS GPRO. CMS proposes the following satisfactory reporting criteria for group practices for the 2017 PQRS payment adjustment (note that options vary depending on group size):

Via the GPRO Web Interface

> For a group practice of 25 or more EPs, report on all measures included in the web interface and populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

Via Qualified Registry

> For a group practice of 2 or more EPs, report at least 9 measures covering at least 3 NQS domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3

NQS domains apply to the EP, then the group practice must report up to 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. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP must report on at least 2 measures contained in the cross-cutting measure set. Measures with a 0 percent performance rate would not be counted.

Via EHR Direct Product or EHR Data Submission Vendor

For a group practice of 2 or more EPs, report 9 measures covering at least 3 NQS domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

Via a Certified Survey Vendor in Addition to a Qualified Registry

For a group practice of 25 or more EPs, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures covering at least 2 NQS domains using a qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 6 measures. Of these 6 measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set.

Via a Certified Survey Vendor in Addition to Direct EHR Product or EHR Data Submission Vendor

For a group practice of 25 or more EPs, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 NQS domains using the direct EHR product that is CEHRT or EHR data submission vendor that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 6 measures. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

Via a Certified Survey Vendor in Addition to the GPRO Web Interface

For a group practice of 25 to 99 EPs, or a group practice of 100 or more EPs, report all CAHPS survey measures via a CMS-certified survey vendor and report on all measures included in the GPRO web interface; and populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive

care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice would be required to report on at least 1 measure for which there is Medicare patient data.

Note that for reporting through the GPRO Web interface, CMS is proposing to increase the sample size for groups of 25-99 EPs from 218 to 248 and to reduce the sample size for groups of 100 or more from 411 to 248. For the smaller groups, CMS believes that there would be increased performance reliabilities and validities gained when changing the minimum reporting requirement to 248 (but does not explain this further). For larger groups, CMS says the reduced sample size would reduce provider reporting burden while still allowing for statistically valid and reliable performance results. For purposes of reporting through the GPRO web interface, CMS proposes to adopt a modified beneficiary attribution methodology that differs slightly from the one used under the Medicare Shared Savings Program. This modified methodology is also being proposed for use under the Value-Based Modifier (discussed below). The modified methodology eliminates the primary care services pre-step that is statutorily required for the Shared Savings Program and includes nurse practitioners, physician assistants, and certified nurse specialists in step 1 rather than step 2 of the attribution process. CMS emphasizes that a group practice will not meet the criteria for satisfactory reporting using the GPRO web interface if the group has no Medicare patients for which any of the GPRO measures are applicable, and advises such groups to participate in the PQRS via another reporting mechanism.

CMS also notes that it again proposes that all group practices comprised of 100 or more EPs that register to participate in the PQRS GPRO, regardless of the reporting mechanism the group practice chooses, would be required to select a CMS-certified vendor to administer the CAHPS for PQRS survey on their behalf. CMS adds that beginning in 2015, it will unfortunately no longer be feasible for CMS to continue to bear the cost of group practices of 100 or more EPs to report the CAHPS for PQRS survey measures. Reporting CAHPS for PQRS would remain optional for smaller groups but if elected, such groups would also need to pay a CMS-certified survey vendor.

The proposed rule also proposes criteria for satisfactory reporting on individual PQRS quality measures for group practices that participate in the GPRO <u>for the 2018 PQRS payment adjustment and subsequent years</u>. In conjunction with other satisfactory reporting criteria CMS establishes in future years, beginning with the 12-month reporting period for the 2018 PQRS payment adjustment, and for subsequent years, group practices of 25 or more EPs that are participating in the GPRO would be required to report and pay for the collection of the CAHPS for PQRS survey measures using a CMS-certified survey vendor.

The proposed rule also addresses the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS). CMS says that “at this time, due to the cost and time it would take to find vendors to collect S-CAHPS data, it is not technically feasible to implement the reporting of the S-CAHPS survey measures for the 2017 PQRS payment

adjustment." ***CMS seeks comments on how to allow for reporting of the S-CAHPS survey measures for the 2018 PQRS payment adjustment and beyond.*** And later in the proposed rule, CMS notes that it would allow and encourage the reporting of the S-CAHPS through a QCDR.

5. PQRS Quality Measures for 2015 and Beyond

CMS notes that it is proposing to drop some PQRS measures because the measure owner/developer has indicated that it will not be able to maintain the measure. However, CMS says that if it learns that a certain measure owner/developer is able to maintain a measure, or another entity is able to maintain the measure in a manner that allows the measure to be available for reporting under the PQRS for the CY 2017 PQRS payment adjustment, CMS proposes to keep the measure. Similarly, if, after display of this proposed rule, CMS discovers additional measures within the current PQRS measure set that a measure owner/developer can no longer maintain, it proposes to remove these measures from the PQRS measure set beginning in 2015.

CMS also notes that it is beginning to group the final measures available for reporting according to specialty and refers readers to the current listing of measures by specialty at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html. CMS emphasizes that EPs are not required to report measures according to these suggested groups of measures. CMS adds that it plans to have a measure subset that specifically addresses multiple chronic conditions.

CMS proposes that, if it discovers errors in the most recently updated electronic measure specifications for a certain measure, it would use the version of electronic measure specifications that immediately precedes the most recently updated electronic measure specifications. With specific reference to the e-measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor Positive Breast Cancer (NQF 0387), CMS will require use of a more recent, updated version of this measure, version CMS140v3.

Table 21 of the proposed rule lists the 18 cross-cutting measures that CMS proposes for use during 2015 and beyond. This table lists the rationale for proposing each of the measures. CMS invites comments on other measures that should be included in this cross-cutting measure set.

Table 22 of the proposed rule lists 28 measures that CMS is proposing to add to the PQRS measure set for CY 2015 and beyond. This table also includes the rationale for proposing each of these measures.

Table 23 of the proposed rule lists 24 current PQRS measures for which CMS is proposing a NQS domain change and the rationale for each proposed change.

Table 24 of the proposed rule lists 73 measures that CMS is proposing to delete from the current PQRS measure set and includes the rationale for each proposed deletion.

Common rationales include performance on a measure is close to 100 percent, the measure represents a clinical concept that CMS does not believe adds clinical value, or the measure steward has indicated it will no longer maintain the measure.

Table 25 of the proposed rule lists 56 PQRS measures for which CMS is proposing to change the way in which the measures will be reported beginning in 2015. In many cases, the option of submitting measure data via claims is being eliminated or an individual measure is proposed for measures group reporting only.

With respect to measures groups, CMS is again proposing to increase the number of measures from a minimum of 4 measures to a minimum of 6, and says it has worked with relevant measure owners and developers on this. CMS also proposes two new measures groups beginning in 2015: the sinusitis measures group and the acute otitis externa measures group. CMS further proposes to remove the following 6 measures groups:

- Perioperative care measures group (CMS says it does not add value to the PQRS and EPs have performance rates close to 100 percent);
- Back pain measures group (CMS says the measure steward is not preparing the measures for re-endorsement by the National Quality Forum and CMS believes that the measures group reflects clinical concepts that do not add clinical value to PQRS);
- Cardiovascular prevention measures group (CMS says a number of the measures in this measures group are proposed for deletion);
- Ischemic vascular disease measures group (a number of the measures in this measures group are proposed for deletion);
- Sleep apnea measures group (the measure steward has said it will no longer maintain a number of the measures in this measures group); and
- Chronic obstructive pulmonary disease measures group (the measure steward has said it will no longer maintain a number of the measures in this measures group).

Tables 26 through 48 of the proposed rule specify the 22 CMS-proposed measures groups, two of which (chronic obstructive pulmonary disease and sleep apnea) are essentially listed contingent on the component measures being maintained by the existing measure steward or another entity. The tables list the proposed measures for each measures group, which range from 6 to 10 measures.

With respect to the GPRO web interface, CMS is proposing to remove 5 existing measures (listed in Table 48 of the proposed rule) and add 9 new measures (listed in Table 49 of the proposed rule). If these proposals are finalized, the GPRO measure set would contain 21 measures.

CMS acknowledges that it previously misclassified the CAHPS for PQRS survey under the care coordination and communication NQS domain and is now correctly classifying it under the Person and Caregiver-Centered Experience and Outcomes domain.

6. QCDR Measure Issues

See earlier discussion in III.K.1 above relating to proposed requirements for reporting outcome, resource use, patient experience of care, and efficiency/appropriate use measures via a QCDR.

CMS proposes that a QCDR must provide to CMS descriptions for the measures for which it will report to CMS for a particular year by no later than March 31 of the applicable reporting period for which the QCDR wishes to submit quality measures data. 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. And the narrative specifications provided must be similar to the narrative specifications CMS provides in its measures list, available at http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2014_PQRS_IndClaimsRegistry_MeasureSpecs_SupportingDocs_12132013.zip.

CMS further proposes that, 15 days following CMS approval of these measure specifications, the QCDR must publicly post the measure specifications for the measures it intends to report for the PQRS using any public format it prefers. In addition, immediately following the posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted.

7. Informal Review

Because PQRS data is used to establish the quality composite of the VM, CMS believes it is necessary to expand the informal review process under PQRS to allow for some limited corrections of the PQRS data to be made. CMS, therefore, proposes to modify the payment adjustment information review deadline to within 30 days of the release of the feedback reports. For example, if the feedback reports for the 2016 payment adjustment (based on data collected for 2014 reporting periods) are released on August 31, 2015, an EP or group practice would be required to submit a request for an informal review by September 30, 2015.

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

- CMS would only allow resubmission of data that was submitted using a third-party vendor using the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms (CMS believes that third-party vendors are more easily able to detect errors than direct users; it will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms).
- CMS would only allow resubmission of data that was already previously submitted to CMS.

- CMS would only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

8. Information Collection Requirements and Impact

CMS estimates that 50 percent of EPs (or approximately 600,000 EPs) will report quality measures data for purposes of the 2017 PQRS payment adjustment. The accounting statement in the proposed rule lists an estimated increase in payment of $234 million in CY 2015 annualized monetized transfers from the federal government to EPs who satisfactorily participate in PQRS but this is not otherwise discussed. And CMS estimates that the total cost for EPs and EPs in group practices using the claims, qualified registry, or EHR PQRS reporting mechanisms in CY 2015 would range from a low of about $124.6 million to a high of about $233 million. And the total annual cost for the 200 group practices reporting via the web-based interface is estimated at $651,200.

CMS assumes that a billing clerk will handle the administrative duties associated with PQRS participation (at a mean hourly wage of $16) and that a computer analyst will handle duties related to reporting PQRS measures (at a mean hourly wage of $41). CMS further estimates that an eligible professional or group practice would spend 5 hours to get ready to participate in PQRS for the first time. This time would be spent on the following: reviewing the PQRS measures list, reviewing the various reporting options, selecting a reporting mechanism and measures on which to report, reviewing the measure specifications, and developing a mechanism for incorporating reporting of selected measures into their office work flow. CMS' estimate of administrative costs assumes that all the preceding tasks would be handled by a billing clerk. CMS further assumes that the time needed to perform all the steps necessary to report each PQRS measure via claims will range from 0.25 minutes to 12 minutes, meaning that the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. CMS further assumes that a physician would report data for an average of 6 cases per measure, meaning that the total cost of claims-based reporting would range from $9.18 to $442.80, with the cost to the median practice estimated at $64.58 per eligible professional. CMS estimates that about 250,000 eligible professionals will participate in the PQRS using the claims-based reporting mechanism in 2015.

CMS estimates that the remainder of the eligible professionals will participate in PQRS using either the qualified registry or qualified clinical data registry options (165,000 EPs combined), EHR-based reporting (50,000 EPs), or the GPRO web interface reporting mechanism (135,000 EPs from 200 group practices). For the qualified registry and QCDR options, CMS says there will be no additional time burden for EPs for group practices because CMS assumes they are reporting data to these registries for reasons other than PQRS. CMS does acknowledge that EPs would need to authorize or instruct a registry to submit quality measures on their behalf and estimates this would require about 5 minutes per EP. For direct reporting via EHR, CMS notes that the EP or group must have access to a CMS specified identity management system, such as IACS, which CMS estimates takes less than 1 hour to obtain. CMS further estimates that

submitting the actual data file for a reporting period would take an EP or group no more than 2 hours.

CMS also estimates that it would take about 6 hours for a group practice to be selected to participate in PQRS GPRO for the applicable year at an estimated cost of $96. The burden associated with a large group practice completing the data submission through the web-based interface is estimated at 79 hours at an estimated cost of $3,160, the same amount estimated in the past despite the proposed change in sample size for web-based interface reporting.

Although CMS is proposing the reporting of CAHPS survey measures using a CMS-certified survey vendor, it does not include this reporting mechanism in its impact statement because the agency believes that EPs wishing to report CAHPS survey measures will do so for purposes other than PQRS.

L. Electronic Health Record (EHR) Incentive Program

In the CY 2014 PFS final rule, CMS finalized the requirement that EPs who report CQMs electronically under the Medicare EHR Incentive Program 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. In response to feedback about the difficulty and expense of having to test and recertify CHERT products to the most recent version of the electronic specifications for the CQMs, CMS is proposing that beginning in CY 2015, EPs would not have to meet this requirement.

EPs must still report the most recent version of the electronic specifications for the CQMs. When establishing this requirement, CMS notes they did not account for instances where errors are discovered in the update electronic measure specifications. CMS proposes that beginning in CY 2015, if CMS discovers errors in the most recently updated electronic measure specifications for a certain measure, they would use the version that immediately preceded the most recent update. CMS notes that with respect to the measure CMS140v2, Breast Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), a substantive error was discovered in the June 2013 version and EPs reporting the measure in CY 2014 needed to use the prior, December 2012 version of this measure. For CY 2015, CMS notes there will be a more recent and corrected version of this measure that EPs will need to use.

In the CY 2014 PFS final rule, CMS finalized a group reporting option for CQMs for the Medicare EHR Incentive Program under which EPs who are part of a Comprehensive Primary Care (CPC) initiative practice site that successfully reports at least nine electronically specified CQMs across three domains for the relevant reporting period and use CEHRT would satisfy the CQM reporting component of meaningful use for the EHR Incentive Program. For CY 2015, CMS is proposing to retain this group reporting option for CPC practice sites but to modify the requirement such that the nine CQMs

reported must cover at least 2 domains. CMS is concerned that the CPC practice sites may not have measures to select that cover three domains.

CMS notes that proposed changes to the EHR Incentive Program would not impact CY 2015 physician payment under the PFS.

M. Medicare Shared Savings Program

With respect to the Medicare Shared Savings Program involving accountable care organizations (ACOs), the proposed rule revisits the current quality performance standard, proposes changes to the quality measures, and seeks comment on future quality performance measures. It would also modify the timeframe between updates to the quality performance benchmarks, establish an additional incentive to reward ACO quality improvement, and make several technical corrections to the regulations in subpart F of Part 425.

1. Proposed Changes to the Quality Measures Used in Establishing Quality Performance Standards that ACOs Must Meet to be Eligible for Shared Savings

CMS proposes to assess ACOs on 37 measures annually (rather than the current 33), effective for the 2015 reporting period (for which data would be reported in early 2016). This would involve the addition of 12 new measures and the retirement of 8 current measures, and corresponding adjustments to the Diabetes and Coronary Artery Disease composite measures. CMS notes that the increased number of measures is accounted for by measures that would be calculated by CMS using administrative claims data or from a patient survey, and that the total number of measures that ACOs would need to directly report through the CMS website interface would decrease by one.

The proposed new measures include the following:

1. CAHPS Stewardship of Patient Resources, which asks the patient whether the care team talked with the patient about prescription medicine costs;
2. Skilled Nursing Facility 30-Day All-Cause Readmission Measure, which would be calculated from claims;
3. All-Cause Unplanned Admissions for Patients with Diabetes Mellitus;
4. All-Cause Unplanned Admissions for Patients with Heart Failure;
5. All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (measures #3-5 are under development through a CMS contract with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation);
6. Depression Remission at Twelve Months (***CMS seeks comments on the inclusion of additional behavioral health measures, such as substance abuse or mental health measures, in future rulemaking cycles***);
7. Diabetes Measure for Foot Exam;
8. Diabetes Measure for Eye Exam;

9. Coronary Artery Disease: Symptom Management (an assessment of patient activity level and management of angina);
10. Coronary Artery Disease: Beta Blocker Therapy—Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF<40%);
11. Coronary Artery Disease: Antiplatelet Therapy, defined as the percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period that were prescribed aspirin or clopidogrel; and
12. Documentation of Current Medications in the Medical Record, which would replace the current medication reconciliation measure because the medical community has indicated to CMS that it is better clinical practice to perform medication reconciliation at every office visit rather than immediately following a hospital discharge.

CMS further proposes to no longer collect data on the following ACO measures:

1. ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility;
2. ACO #22, Diabetes Composite Measure: Hemoglobin A1c control (<8 percent), because CMS has concerns that the HbA1c level monitored in this measure is considered too low to comprehensively evaluate HbA1c control for the frail elderly population;
3. ACO #24, Diabetes Composite: Blood Pressure (<140/90), because CMS believes there is clinical overlap with ACO #28, Hypertension: Blood Pressure Control;
4. ACO #25, Diabetes Composite: Tobacco Non-Use, because CMS believes this measure is somewhat duplicative of ACO #17, Tobacco Use Assessment and Tobacco Cessation Intervention;
5. ACO #23, Diabetes Composite: Low Density Lipoprotein (<100), due to the release of a new clinical guideline by the American College of Cardiology and American Heart Association;
6. ACO #29, Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (same rationale as for #5);
7. ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic, which is being replaced by the new measure for antiplatelet therapy; and
8. ACO #32, Coronary Artery Disease Composite: Drug Therapy for Lowering LDL Cholesterol (same rationale as for #5 and #6).

CMS also proposes to modify the name and specifications for existing ACO measure #11, which would now read Percent of PCPs [Primary Care Physicians] who Successfully Meet Meaningful Use Requirements rather than Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment. This measure would continue to be doubly weighted.

Table 50 of the proposed rule lists all 37 measures that would apply, gives the method of data submission for each measure, and notes the ACO performance years in which only measure reporting is required vs. those performance years in which actual ACO performance on a measure would be assessed. CMS says that all 37 measures would

be phased in for ACOs with 2015 start dates per the pay for performance phase in information provided in Table 50. CMS notes that ACOs with start dates before 2015 would be responsible only for complete and accurate reporting of the new measures for the 2015 performance year. Tables 51 and 52 of the proposed rule provide the current and proposed number of measures by domain and total points and domain weights for scoring purposes, respectively.

Given the general concerns around composite measures and their use, ***CMS seeks comments on how it combines and incorporates component measure scoring for the composite, especially whether stakeholders have concerns about including ACO #27, Diabetes Mellitus: Hemoglobin A1c Poor Control, a reverse-scored measure, in the Diabetes Composite, and whether there are any methodological considerations the agency should consider when including a reverse-scored measure in composites.***

CMS notes that an ACO that transitions to a new agreement period would continue to be assessed on the quality performance standard that would otherwise apply to an ACO in the third performance year of its first agreement period (that is, the ACO would be responsible for performance on a measure, and not revert to a complete and accurate reporting standard).

CMS also proposes to reduce the sample for each ACO measure reported through the CMS web interface, from 411 to 248, as it is proposing to do under the PQRS GPRO (discussed in section III.K above).

2. Request for Comments for Future Quality Measures

CMS says it is interested in public comment on additional measures that the agency may consider in future rulemaking. CMS particularly welcomes comments on the following issues:

- Gaps in measures and additional specific measures, such as whether there are additional measures that might be used to assess an ACO's performance with respect to care coordination in post-acute care and other settings, and measures that address the quality of care in the various different settings that may be part of an ACO;
- Caregiver experience of care;
- Alignment with VM measures (CMS notes that consistent with section 1848(p)(4)(B)(iii)(II), which requires application of the VM to all physicians and groups of physicians beginning not later than January 1, 2017, it proposes to start applying the VM to physicians participating in ACOs beginning in 2017, and seeks comment on whether there are synergies that can be created by aligning the ACO quality measures set with the measures used under the VM, such as the Composite of Acute Prevention Quality Indicators and the Composite of Chronic Prevention Quality Indicators, perhaps as a future replacement for the two ACO claims based ambulatory sensitive conditions admissions measures);
- Specific measures to assess care in the frail elderly population;

- Utilization, more specifically, whether it is sufficient to provide periodic feedback to ACOs regarding utilization or whether utilization measures should be used to assess ACO performance as an added incentive to provide more efficient care, with CMS especially interested in specific comments on what measures would be most appropriate for this purpose and how to risk adjust such measures;
- Health outcomes, including comments regarding inclusion of a self-reported health and functional status measure, the appropriateness of using a tool such as the Health Outcomes Survey for health plans, which assesses changes in the physical and mental health of individual beneficiaries over time, and suggestions for alternatives to self-reported measures;
- Measures for retirement, such as "topped out" measures; and
- Additional public health measures, with CMS saying it is considering adding "Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling" (NQF #2152).

3. Accelerating Health Information Technology

CMS notes that EPs participating in an ACO under the Medicare Shared Savings Program who extract from CEHRT the data necessary for the ACO to satisfy the quality reporting requirements of the Shared Savings Program would satisfy the clinical quality measure (CQM) reporting component of meaningful use as a group for the Medicare EHR Incentive Program. Of course, in addition to submitting CQMs as part of an ACO, EPs would have to individually satisfy the other objectives and associated measures for their respective stage of meaningful use. CMS also clarifies that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all its CQM data from a CEHRT and report it to the ACO, and the ACO must also report the GPRO web interface measures and satisfy the reporting requirements under the Shared Savings Program in order for its EPs to satisfy the CQM reporting component of meaningful use. CMS proposes to amend its regulations to provide for this alignment and says it intends to take steps in the future to better align and integrate EHR use into quality reporting under the Shared Savings Program.

CMS acknowledges that there are operational constraints that must be considered when developing policies related to electronic reporting of quality measures under the Shared Savings Program, including the fact that many ACO legal entities do not provide direct health care services and therefore may not thus far have had a need for an EHR, ACO participants and ACO providers/suppliers may be at different levels of EHR adoption, and may have chosen different platforms that are not yet seamlessly interoperable. CMS identifies a number of possible options for implementing electronic reporting of quality measures: EPs within each ACO participant individually submitting EHR data to CMS; each ACO participant reporting as a group; the ACO aggregating EHR data from its ACO participants and then submitting the data to CMS; and use of a data submission vendor that would be responsible for aggregating and submitting data on the ACO's behalf.

CMS says it is not proposing new requirements regarding EHR based reporting under the Shared Savings Program at this time, ***but welcomes suggestions and comments about these issues, especially on the feasibility of an ACO to be a convener and submitter of quality measures through an EHR or alternative method of electronically reporting quality measures. CMS also welcomes suggestions on alternative ways that it might implement EHR-based reporting of quality measures in the Shared Savings Program and comments on whether such reporting should be a requirement for all Shared Savings Program ACOs or phased in gradually. CMS also seeks comment on whether ACO providers/suppliers could use a local registry-like version of the GPRO web interface to capture relevant clinical information and to monitor performance on all Medicare patients throughout the year and to more easily report quality data to CMS annually.***

4. Quality Performance Benchmarks

CMS proposes revisions for benchmarking measures that are "topped out" because it agrees that it is possible that smaller practices or practices with smaller populations may be able to achieve higher levels of performance more easily that larger practices and organizations with larger patient populations. Thus, when the national fee-for-service (FFS) data results in the 90th percentile for a measure being greater than or equal to 95 percent, CMS proposes to use flat percentages for the measure, similar to the current policy under which it uses flat percentages when the 60th percentile is greater than 80 percent. CMS invites comments on other potential approaches for addressing topped out measures, such as dropping such measures, folding them into composites, or retaining them but making them pay for reporting only.

CMS further proposes to update benchmarks every 2 years, but adds that it may revisit this policy as more ACOs enter the program, more FFS data is collected which could help the agency better understand to what extent benchmarks should vary from year to year, or if it makes any future proposals regarding the use of Medicare Advantage data for setting benchmarks. More specifically, CMS says that it would reset the benchmarks for all ACOs based on data for the 2014 reporting period (reported during 2015) and the updated benchmarks would apply for the 2016 and 2017 performance years. Nonetheless, ***CMS invites comments on the appropriate number of years a benchmark should remain stable before it is updated, when annual updates might be appropriate, and whether data from multiple years should be used in updating benchmarks to help make them more stable.*** Table 54 of the proposed rule (reproduced below) gives the proposed timeline for setting and updating quality performance benchmarks under the Medicare Shared Savings Program.

TABLE 54: Proposed Timeline for Setting and Updating Quality Performance Benchmarks

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

5. Rewarding Quality Improvement

CMS says that ACOs and other stakeholders have been requesting an additional explicit reward for those ACOs that improve their performance from one year to the next. CMS is proposing to provide for this and notes that it looked to the Medicare Advantage five star rating program for a potential model. This rating program computes an improvement change score which is defined as the score for a measure in a performance year minus the score in a previous performance year and then measures each plan's net quality improvement by calculating the total number of significantly improved quality measures and subtracting the total number of significantly declined quality measures.

Thus, CMS proposes to add a quality improvement measure to award bonus points for quality improvement to each of the existing four quality measure domains. CMS would award an ACO up to two additional bonus points (on a sliding scale basis) for quality performance improvement but the total possible points that could be achieved in a domain could not exceed the current maximum. And ACOs would achieve bonus points in a domain if they achieve statistically significant levels of quality improvement for measures within the domain. For purposes of determining quality improvement and awarding bonus points, CMS proposes to include all of the individual measures within a domain, including both pay-for-reporting measures and pay-for-performance measures. CMS would determine whether there was a significant improvement or decline by applying a common standard statistical test, and refers readers to the discussion of the t-test for calculating the Medicare Advantage quality improvement measure in "Medicare 2014 Part C and D Star Rating Technical Notes," Attachment I, page 80, which can be accessed at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

CMS notes that in developing its proposal to award bonus points for quality improvement, it considered several alternatives, including not awarding bonus points but instead including a computed quality improvement measure that would be incorporated into the current scoring methodology, or providing an even greater additional incentive by increasing the total possible bonus points, perhaps up to 4 points. CMS also acknowledges some concerns about using "pay for reporting" data, given that the accuracy does not affect an ACO's quality performance score in the first

performance year. As a result, CMS says it considered applying the quality improvement score only to those ACOs that have completed at least two performance years but did not select this approach because it wanted to provide an incentive that would apply as soon as possible in the agreement period. Nonetheless, CMS welcomes comments on the alternative approaches described above as well as any other possible approaches, and also welcomes suggestions on how the Shared Savings Program might integrate elements of other quality improvement methodologies, such as those employed by the Hospital Value-Based Purchasing Program or Medicare Advantage.

6. Technical Corrections

CMS proposes to eliminate a reference to a non-existent paragraph (c) of §425.216 and instead refer to §425.216 generally, correct a typographical error in §425.502(d)(2)(ii), and make a technical correction to §425.502(a)(2) to state that ACO performance will be assessed based on the quality performance benchmark and minimum attainment level for certain measures (not only on the latter).

N. Physician Value-Based Payment Modifier (VM) and the Physician Feedback Reporting Program

Beginning January 1, 2015, the Secretary is required to apply a VM to specific physicians and groups of physicians the Secretary determines are appropriate. Not later than January 1, 2017, the Secretary is required to apply the VM to all physicians and groups of physicians. On or after January 1, 2017, the Secretary has the discretion to apply the VM to other eligible professionals.

In this rule, CMS is proposing to apply the VM to all physicians and nonphysician eligible professionals.

1. Proposals for the VM

As discussed below in greater detail, CMS makes the following proposals for the VM:

- Apply the VM to all physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to solo practitioners starting in CY 2017.
- Make quality-tiering mandatory for groups and solo practitioners with Category 1 for the CY 2017 VM. Groups with 10 or more eligible professionals would be subject to upward, neutral, or downward adjustments. Groups with between 2 and 9 eligible professionals and solo practitioners would be subject to only an upward or neutral adjustment.
- Apply the VM to physicians and nonphysician eligible professionals participating in the Shared Savings Program, the Pioneer ACO Model, the CPC Initiative, or other similar CMS initiatives starting in CY 2017.
- Clarifies the exclusion of non-assigned claims for non-participating providers from the VM.
- Increase the amount of payment at risk under the VM from 2.0 percent in CY

2016 to 4.0 percent in CY 2017.

- Align the quality measures and quality reporting mechanisms for the VM with those available to groups and individuals under the PQRS during the CY 2015 performance period.
- Expand the current informal inquiry process to allow additional corrections for the CY 2015 payment adjustment period.
- Address the concerns raised by NQF regarding the per capital cost measures in the cost composite

CMS also seeks comment about how to include hospital-based physicians in the VM.

a. Group Size

CMS proposes that beginning with CY 2017, the VM would be applied to physician and nonphysician eligible professionals in groups with 2 or more eligible professionals and to solo practitioners based on the CY 2015 performance period. CMS estimates that this proposal will affect approximately 83,500 groups and 210,000 solo practitioners (as identified by their TINs) that consist of approximately 815,000 physicians and 315,000 nonphysician eligible professionals.

- Physicians are defined as in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.
- Eligible professional are defined in section 1848(k)(3)(B) of the Act as any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act: physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse mid-wife, clinical social worker, clinical psychologist, registered dietician, or nutritional professional; (3) a physical or occupational therapist or qualified speech-language pathologist; or (4) a qualified audiologist.
- CMS will define a group of physicians as a single TIN with 2 or more eligible professionals, as identified by their individual NPI and have reassigned their Medicare billing rights to the TIN. During the payment adjustment period, all the nonphysician eligible professionals who bill under a group's TIN would be subject to the same VM that would apply to the physicians who bill under the TIN.
- CMS will define a solo practitioner as a single TIN with 1 eligible professional as identified by an individual NPI billing under the TIN.

CMS discusses the statistical reliability analysis conducted on the PQRS quality measures in the 2010 and 2011 group and individual Quality Resource Use Reports (QRURs) which demonstrated high reliability for both the group and individual measures. Thus, with the exception of the all cause hospital readmission measure (discussed below in the section h, quality), CMS believes that the PQRS quality measures for groups with 2 or more eligible professionals and solo practitioners will also be reliable.

CMS also conducted statistical reliability on the cost measures contained in the 2010 and 2011 group and individual QRURs, these reports contained the same 5 per capita cost measures used in the VM, and found statistically reliability at a high level for all of the cost measures in the individual and group reports. In the CY 2014 PFS final rule, CMS finalized including the Medicare Spending per Beneficiary (MSPB) measure in the cost composite of the VM and the use of a cost comparison approach which considers the medical specialty composition of the physicians. Based on analysis of CY 2012 claims, CMS believes they will be able to calculate a cost composite score for a significant number of groups and solo practitioners. If CMS is unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the VM, and thus are unable to calculate at least one cost measures with at least 20 cases, then the group's cost composite score is classified as "average" under the quality tierring methodology. Beginning in CY 2017, CMS proposes to apply the same policy to all groups and solo practitioners: a group or solo practitioner would receive a cost composite score as "average" if the group or solo practitioner does not have at least one cost measure with at least 20 cases.

CMS notes that all groups and solo practitioners will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. Later this summer, CMS plans to disseminate QRURs based on CY 2013 data to all groups of physicians and physicians who are in solo practice. These QRURS will contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and will show how all TINs would perform under the VM. The QRURs will also include information about the TIN's performance on the MSPB measure, individually-reported PQRS measures and the specialty-adjusted measures. Similar information will be disseminated during the summer of 2015 based on CY 2014 data. CMS notes that their proposal to hold harmless groups with between 2 and 9 eligible professionals and solo practitioners from any downward payment adjustment under quality-tiering in CY 2017 would likely mitigate unintended consequences that could occur.

b. Application of the VM to Nonphysician EPs

CMS proposes that beginning with CY 2017, the VM would be applied to groups that consist of only nonphysician eligible professionals and to solo practitioners who are nonphysician eligible professionals based on the CY 2015 performance period.

- CMS proposes that physicians and nonphysician eligible professionals would be subject to the same VM policies established in earlier rulemakings and under 42 CFR part 414, subpart N.
- The quality of care composite would be based on the quality data submitted under the PQRS at the group or individual level in accordance with PQRS policy.
- The cost composite would be based on the beneficiary attribution methodology and if a cost composite cannot be calculated for a group or

solo practitioner, CMS proposes to classify the group or solo practitioner's cost composite as "average".

c. Approach to Setting the VM Adjustment Based on PQRS Participation

1. Categorization based on PQRS Participation

Similar to the categorization of groups of physicians eligible for the CY 2016 VM, CMS proposes to use a two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners (PQRS reporting requirements are discussed in section K of this summary).

Category 1

For purposes of the CY 2017 VM, CMS proposes that Category 1 would include:

- Groups that meet the criteria for satisfactory reporting data on PQRS quality measures via the GPRO (through use of the web-interface, EHR, or registry reporting mechanism)
- Groups that do not register to participate in the PQRS GPRO in CY 2015 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, EHR, or registry reporting mechanism) for the CY 2017 payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2017 PQRS payment adjustment.
- Solo practitioners that meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, EHR or registry reporting mechanisms) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2017 PQRS payment adjustment.

CMS intends to align the criteria for inclusion in Category 1 with the criteria that are established for the CY 2017 PQRS payment adjustment.

Category 2

CMS proposes that Category 2 would include those groups and solo practitioners that are subject to the CY 2017 VM and do not meet the criteria for Category 1. As discussed below, CMS is proposing a -4.0 percent VM to groups with two or more eligible professionals and solo practitioners that are in Category 2.

2. Quality-Tiering Methodology

CMS calculates the VM using a quality-tiering approach that requires the development of quality and cost composites. For the CY 2017 VM, CMS proposes to apply the quality tiering methodology to all groups in Category 1 with a distinction based on group size.

- Groups with between 2 and 9 eligible professionals and solo practitioners would be subject to only an upward or neutral adjustment. These groups and solo practitioners would be held harmless from any downward adjustment. CMS notes that they anticipate future rulemaking proposals would apply the CY 2018 VM with both upward, neutral or downward adjustments based on a performance period of CY 2016.

- Groups of physicians with between 10 and 99 eligible professionals would be subject to upward, neutral or downward adjustment.

Based on an analysis of CY 2012 claims, CMS estimates for eligible professionals in a Category I TIN that approximately 6 would be classified in quality tiers to earn an upward adjustment, approximately 11 percent would be classified in quality tiers to earn a downward adjustment and approximately 83 percent would receive no payment adjustment in CY 2017. CMS concludes that quality-tiering identifies a small number of groups and solo practitioners that are outliers, thus limiting any widespread unintended consequences.

d. Application of the VM to Physicians and Nonphysician Eligible Professionals that Participate in the Shared Savings Program, the Pioneer ACO Model, the CPC Initiative, or Other Similar CMS Initiatives

Discussed below is CMS' proposal to apply the VM beginning in the CY 2017 payment adjustment period to physicians and nonphysician eligible professionals in groups and solo practitioners, participating in the Shared Savings Program, Pioneer ACO Models, the CPC Initiative or other similar CMS initiatives.

1. Physicians and Nonphysician Eligible Professionals that Participate in ACOs Under the Shared Savings Program

Beginning with the CY 2017 payment adjustment period, CMS proposes to apply the VM to physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners that participate in the Shared Savings Program as part of an ACO (as provided in section 1899 of the Act).

- CMS proposes to apply the same VM to physicians and nonphysician eligible professionals in groups and to physician and nonphysician eligible professionals who are solo practitioners that participate in the ACO during the payment adjustment period.

A summary of CMS' proposal is shown in Table 56 and reproduced below at the end of this section (Section N).

Cost Composite

- CMS proposes to classify the cost composite for the VM as "average cost" for groups and solo practitioners participating in the Shared Sayings

Program (as identified by the ACO's participant TINs) regardless of whether they participated in the Shared Savings Program during the performance period (for example, in CY 2015 for the CY 2017 VM). Because of the differences used to calculate the cost benchmarks under the Shared Savings Program and the VM, CMS does not think it would be appropriate to apply the quality-tiering methodology to calculate the cost composite.

- CMS proposes to apply the quality-tiering methodology to calculate the cost composite for the VM for groups and solo practitioners that participated in the Shared Savings Program during the performance period but no longer participate in the Shared Savings Program during the payment adjustment period. CMS states this is appropriate because during the payment adjustment period, the cost benchmarks would only be calculated under the VM.

Quality of Care Composite: CMS discusses various scenarios depending upon whether or not the group or solo practitioner is participating in the ACO during the performance period or during the payment adjustment period.

- CMS proposes to calculate the quality of care composite score based on the quality-tiering methodology using quality data submitted by the ACO from the performance period and apply the same score to all of the groups and solo practitioners under the ACO during the payment adjustment period. Thus for CY 2017, CMS proposes to calculate the quality of care composite score for the CY 2017 VM for all groups and solo practitioners participating in the ACO in CY 2017 based on the ACO's CY 2015 quality data. As discussed below, CMS is proposing to exclude the claims-based outcomes measures from the calculation of the quality of care composite score.

- For groups and solo practitioners that participate in the ACO during the payment adjustment period) and either did not participate in the Shared Savings Program or were part of a different ACO during the performance period, CMS proposes to calculate the quality of care composite score based on the quality data submitted by the ACO from the performance period. CMS states this is consistent with their policy not to "track" or "carry" an individual professional's performance from one TIN to another.

- If the ACO exists during the payment adjustment period but did not exist during the performance period, CMS proposes to classify the quality of care composite for all groups and solo practitioners that participate in the ACO during the payment adjustment period as 'average quality" for the payment adjustment period.

- For groups and solo practitioners that participate in the ACO during the

performance period but no longer participate in the Shared Savings Program during payment adjustment period, CMS proposes to classify the quality of care composite as "average quality" for the VM for the payment adjustment period.

Quality-Tiering Methodology

CMS proposes to follow the same quality-tiering methodology for groups and solo practitioners regardless of whether or not they participated in ACOs during the Shared Savings Program during the CY 2017 payment adjustment period.

- Groups with between 2 and 9 eligible professionals and solo practitioners would be subject to an upward or neutral adjustment. These groups and solo practitioners would be held harmless from any downward adjustment.
- Groups with between 10 and 99 eligible professionals would be subject to upward, neutral or downward adjustment.
- CMS also proposes that groups and solo practitioners participating in ACOs would be eligible for the additional upward payment adjustment of +1.0x for caring for high-risk beneficiaries (discussed below).

2. Physicians and Nonphysician Eligible Professionals that Participate in the Pioneer ACO Model, the Comprehensive Primary Care (CPC) Initiative, or Other Similar CMS Initiatives

Beginning with the CY 2017 payment adjustment period, CMS proposes to apply the VM to physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the CPC Initiatives during the relevant performance period.

- CMS proposes to apply the same VM to physicians and nonphysician eligible professionals in groups and to physician and nonphysician eligible professionals who are solo practitioners that participant in the ACO during the payment adjustment period.

A summary of CMS' proposal is shown in Table 57 and reproduced below at the end of this section (Section N).

Cost Composite

- CMS proposes to classify the cost composite for the VM as "average cost" for groups and solo practitioners participating in the Shared Sayings Program (as identified by the ACO's participant TINs) regardless of whether they participated in the Shared Savings Program during the performance period. Because of the differences used to calculate the cost benchmarks under the Shared Savings Program and the VM, CMS does not think it would be appropriate to apply the quality-tiering methodology to calculate the cost composite.

- CMS proposes to apply the quality-tiering methodology to calculate the cost composite for the VM for groups and solo practitioners that participated in the Shared Savings Program during the performance period but no longer participate in the Shared Savings Program during the payment adjustment period. CMS states this is appropriate because during the payment adjustment period, the cost benchmarks would only be calculated under the VM.

CMS discusses various scenarios depending upon whether or not the group or solo practitioner is participating in the Pioneer ACO or CPC Initiative during the performance period or during the payment adjustment period.

- Groups and solo practitioners that participate in the model during the performance period and do not participate in the Shared Savings Program or other CMS initiatives during the payment adjustment period. CMS proposes to calculate the quality of care composite based on three scenarios:
    - Scenario 1: If the group participates in the PQRS as a group practice under the PQRS during the performance period and meets the satisfactory reporting of data, CMS proposes to use the PQRS GPRO data to calculate the group's quality of care composite. If the group does not meet the criteria for satisfactory reporting of data then the group would fall in Category 2.

    - Scenario 2: If the group does not report under the PQRS GPRO during the performance period and includes one or more eligible professionals that participates in a Pioneer ACO or the CPC Initiative during the performance period, as well as other eligible professionals that do not participate in these initiatives, and at least 50 percent of all eligible professionals in a group satisfactory report quality date (as proposed in Section K), CMS proposes to use the data to calculate a quality of care composite.
        - CMS proposes to assign the group a composite that is the higher of "average quality" or the group's actual classification as determined under the quality-tiering methodology. Based on results from the first performance year, CMS reports these initiatives have performed better than the benchmark rates for FFS beneficiaries and CMS states they want to ensure that these groups are at least considered to have "average" quality. CMS does not believe it is appropriate to classify a group as "low" because this might be due, in part, to lacking PQRS data of higher performing eligible professionals who are reporting through initiatives.
        - CMS proposes to apply the same composite to all eligible professionals that bill under the group's TIN during the

payment adjustment period, regardless of whether they participated in the model during the performance period. If less than 50 percent of all eligible professionals satisfactory report quality data then the group would fall in Category 2.

CMS acknowledges that eligible professionals participating in these initiatives submit quality data but CMS is unable to operationally integrate the data from these initiatives with the VM program due to system constraints and the nature of the reporting.

CMS also considered two alternatives to this proposal. One alternative considered assigning these groups a composite of "average" without consideration of any PQRS data but CMS rejected this because they believe they should use all available quality data. The other alternative was assigning a quality composite of "average" to groups where less than 50 percent of all eligible professionals meet the criteria for satisfactory reporting of data on PQRS measures as individuals because CMS would not have data for more than half of the group.

CMS notes that in a group with a disproportionately large number of eligible professionals participating in an initiative, the above proposals result in the use of PQRS data reported by a relatively small number of eligible professionals who are not participating in the initiative determine the quality of care composite of the group. **CMS seeks comment on the degree to which this occurs, the appropriateness of their proposal, and alternatives to their proposal.**

- Scenario 3: If a group does not report under the PQRS GPRO, consists entirely of eligible professionals that participate in the initiative, and successfully report quality data under the model for the performance period, CMS proposes to classify the group composite as "average" quality. CMS also proposes to classify as "average" solo practitioners that participate in the initiative and successfully report quality data to CMS. CMS proposes to apply the same composite to all eligible professionals that bill under the group's TIN during the payment adjustment period. If a group or solo practitioner do not successfully report quality data, CMS proposes they would fall in Category 2. CMS considered an alternative to assign "average" quality instead of assignment to Category 2 but rejected this because this would not be consistent with the VM policies and may create inappropriate incentives.

CMS proposes to calculate the cost composite for the VM for the payment adjustment period based on a group's and solo practitioner's

performance on the cost measures during the performance period.

- Groups and solo practitioners that participate in the Pioneer ACO model or the CPC Initiative during the performance period and participate in other similar CMS initiatives during the payment adjustment period (but not the Shared Savings Program).
  CMS proposes to calculate the quality of care composite based on the three scenarios discussed above and displayed in Table 57.

  CMS proposes to calculate the cost composite for these groups and solo practitioners for the payment adjustment period as "average" costs. CMS believes that calculating s cost composite based on the quality-tiering methodology may create two sets of standards for evaluating their cost performance. CMS notes that if they think a different approach would be more appropriate they would address that in future rulemaking.

- Groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period and participate in an ACO under the Shared Savings Program during the payment adjustment period.
  CMS proposes to calculate the quality of care composite using the quality data submitted by the ACO from the performance period. For groups and solo practitioner that are participating in an ACO during the payment adjustment period that did not exist during the performance period, CMS proposes to classify the composite as "average" quality because CMS lacks data from the ACO for that performance period.

  CMS proposes to calculate the cost composite for these groups and solo practitioners for the payment adjustment period as "average" costs.

Quality-Tiering Methodology

CMS proposes to follow the same quality-tiering methodology for groups and solo practitioners regardless of whether or not they participate in ACOs during the Shared Savings Program during the CY 2017 payment adjustment period.

- Groups with between 2 and 9 eligible professionals and solo practitioners would be subject to an upward or neutral adjustment. These groups and solo practitioners would be held harmless from any downward adjustment.
- Groups with between 10 and 99 eligible professionals would be subject to upward, neutral or downward adjustment.
- CMS also proposed that groups and solo practitioners participating in ACOs would be eligible for the additional upward payment adjustment of +1.0x for caring for high-risk beneficiaries (discussed below).

Application of the VM to Other CMMI Models or CMS Initiatives

Beginning with the CY 2017 payment adjustment period, CMS proposes to

apply the same VM to physicians and nonphysician eligible professionals to groups with 2 or more eligible professionals and to physician and nonphysician eligible professionals who are solo practitioners that participant in other similar CMMI models or CMS initiatives during the relevant performance period for the VM in accordance with the proposed policies describe above for the Pioneer ACO Model and the CPC Initiative.

CMS acknowledges they are unable to propose an exhaustive list of models and proposes the following general criteria to determine whether a model or initiative would fall in this "other similar" category and thus be subject to the policies described above:

- The model or initiative evaluated the quality of care and/or reports reporting on quality measures;
- The model or initiative evaluated the cost of care and/or reports reporting on cost measures;
- Participants in the model or initiative receive payment based at least in part on their performance on quality and/or cost measures;
- Potential for conflict between the methodologies used for the VM and the methodologies used for the model or initiative; or
- Other relevant factors specific to a model or initiative.

CMS notes that the proposed criteria are intended to serve as a general framework for evaluating models and initiatives. CMS seeks public comment on these or other criteria for determining which models or initiatives should be classified as "other similar" models for the purposes of applying the proposed policies for the Pioneer ACO Model and the CPC Initiative. If CMS determines that a model or initiative falls under the "other similar" category finalized after reviewing public comment, CMS proposes to provide notice to participants through the methods of communication that are typically used for the model or initiative. CMS would use future rulemaking if they believe a different approach to applying the VM would be appropriate for a model or initiative.

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

CMS proposes to clarify that starting in CY 2015, they would apply the VM only to assigned service and not to non-assigned services. CMS believes it is important that beneficiary cost-sharing should not be affected by the VM and that the VM should apply only to the amount Medicare pays to physicians. Additionally, if the proposal to expand the VM to nonphysician eligible professionals is finalized, CMS notes they would likely apply the VM only to services billed on an assignment related basis and not to non-assigned services.

Participating physicians agree to accept the Medicare approved amount as payment in full and charge the beneficiary only the Medicare deductible and

coinsurance amount. Non-participating physicians have not signed an agreement to accept assignment but can choose to accept assignment for individual services. For assigned claims, Medicare makes payment directly to the physician. For non-assigned services, Medicare makes payment directly to the beneficiary and the physician receives all payment for a non-assigned services directly from the beneficiary. If the VM applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the VM is positive and decreased when the VM is negative; this would directly affect beneficiaries and not physicians which is contrary to the intent of the VM. CMS notes that over 99 percent of Medicare physician services are billed on an assignment related basis by both participating and non-participating physicians and other suppliers. CMS does not expect this proposed clarification would likely impact a decision to participate in Medicare or accept assignment for a particular claim.

f. Payment Adjustment Amount

Section 1848(p)(4)(C) of the Act requires the VM to be implemented in a budget neutral manner. In the CY 2014 PFS FR, CMS adopted a policy to apply a maximum downward adjustment of 2.0 percent for the CY 2016 VM for 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. CMS received comments suggesting that the payment adjustment under the VM must be significantly to drive physician behavior toward achieving high quality and low cost and that the VM should be increased incrementally from 2.0 percent and subject to annual review.

In CY 2017, CMS proposes to increase the downward adjustment under the VM by doubling the amount of payment at risk from 2.0 percent in CY 2016 to 4.0 percent in CY 2017. For CY 2017, CMS proposes to:

- Apply a -4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2.
- Increase the maximum downward adjustment under the quality-tiering methodology in CY 2017 to -4.0 percent for groups and solo practitioners classified as either low quality/average cost or average quality/high cost. As discussed above, CMS is proposing to hold solo practitioners and groups with between 2 and 9 eligible professional in Category 1 harmless from any downward adjustments in CY 2017.
- Increase the maximum upward adjustment under the quality-tiering methodology in CY 2107 to +4.0 for groups and solo practitioners classified as high quality/low cost and to set the adjustment to +2.0 for groups and solo practitioners as either average quality/low cost or high quality/average costs.
- Provide an additional upward payment adjustment of +1.0 to groups and

solo practitioner that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population).

Table 58, reproduced below, shows the proposed quality-tiering payment adjustment amounts for CY 2017 based on CY 2015 performance.

TABLE 58: CY 2017 Value-Based Payment Modifier Amounts

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0%	+2.0x*	+4.0x*
Average Cost	-2.0%	+0.0%	+2.0x*
High Cost	-4.0%	-2.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System

As discussed above, CMS proposes to apply the VM to physicians and nonphysician eligible professionals that participate in the Shared Savings Program beginning with the CY 2017 payment adjustment period. CMS notes they will have the final list of ACOs that will participate in the Shared Savings Program during the payment adjustment period and their participant TINs during the fall of CY 2016; this final list, however, may not be available until after the beginning of the payment adjustment period. Therefore, CMS proposes to calculate preliminary payment adjustment factors ("x" in Table 58) prior to the beginning of the payment adjustment period and subsequently finalize the payment adjustment factors after the final ACO participation list is completed. CMS also notes the final payment adjustment factors may be updated depending on the outcome of the informal inquiry process described below (Section i).

g. Performance Period

In the CY 2014 PFS FR, CMS adopted that performance on quality and cost measures in CY 2015 will be used to calculate the VM that is applied to items and devices for which payment is made under the PFS during CY 2017.

h. Quality Measures

PQRS Reporting Mechanisms: For the VM in CY 2017, CMS proposes to include all of the PQRS GPRO reporting mechanisms available to groups for the PQRS reporting periods in CY 2015 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2015. (These reporting mechanisms are described in Tables 21 through 49 of the proposed rule.)

PQRS Quality Measures: For the VM in CY 2017, CMS proposes to use all of the quality measures that are available to be reported under the various PQR reporting mechanisms to calculate a group or solo practitioner's VM in CY 2017 to the extent that a group (including the "50 percent option") or solo practitioner submit data on these measures. (These PQRS quality measures are described in Tables 21 through 49 of the proposed rule.) CMS also proposes:

- Groups with 2 or more eligible professionals would be able to elect to include the patient experience of care measured collected through the PQRS CAPHS survey for CY 2015
- Continue to include the three outcome measures in the quality measures: (1) composite of rates of potentially preventable hospital admissions for heart failure (HF), chronic obstructive pulmonary disease (COPD) and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections (UTIs), and bacterial pneumonia; and (3) rated of an all-cause hospital readmissions measure.
- Groups that are assessed under the "50 percent option" to classify the group's composite score as "average" under the quality-tiering methodology, if all of the eligible professionals in the group satisfactorily participate in a PQRS qualified clinical data registry in CY 2015 and CMS is not able to receive quality performance data. If some eligible professionals in the group report data using PQRS reporting mechanism other than the clinical data registry, CMS would calculate the group's score based on the reported performance data that CMS obtains.

In the CY 2013 PFS FR, CMS finalized a policy that if a measure is new to the PQRS, they will be unable to calculate a benchmark, and performance on that measure will not be included in the quality composite. CMS proposes to apply that policy to measures reported through a PQRS qualified clinical data registry that are new to PQRS (defined as measures that were not previously reported in PQRS). CMS proposes that this would apply beginning with the measures reported through a PQRS qualified clinical data registry in the CY 2014 performance period for the CY 2016 payment adjustment period.

CMS also notes the PQRS administrative claims option is no longer available through PQRS and they propose to clarify that they calculate benchmarks for those outcomes described in §414.1230 using the national mean for a measure's performance rate during the year prior to the performance period in accordance with §414.1250(b).

Quality Measures for the Shared Savings Program: CMS notes there is substantial overlap between the quality measures used to evaluate ACOs under the Shared Savings Program and those used in the PQRS program and for the VM. For the CY 2017 payment adjustment period and subsequent payment adjustment periods to determine a quality composite for the VM for groups and

solo practitioner participating in an ACO, CMS proposes to use the quality measures that are identical to the two programs.

- For the CY 2017 payment adjustment period, CMS proposes to use the PQRS GPRO Web Interface measures and the outcomes measures described at §414.1230(c) to determine a quality composite for groups and solo practitioners. Because in CY 2015 the ACO GPRO measures and PQRS GPRO Web Interface measures will be the same, CMS proposes to use the GPRO Web Interface measures reported by ACOs in determining the quality composite.
- CMS proposes to use the all-cause hospital readmission measure calculated for ACOs in the VM for the CY 2017 payment adjustment period. CMS believes the all-cause hospital readmission measure for ACOs is equivalent to the measure adopted for the VM.
- Not to include the outcome measures that are not currently calculated for ACOs: (1) composite or rates of potentially preventable hospital admissions for HF, COPD, and diabetes; and (2) a composite rate of potentially preventable hospital admissions for dehydration, UTIs, and bacterial pneumonia.

To determine the standardized scores for these quality measures proposed, CMS proposes to apply the VM benchmarks, which are the national mean for a measure's performance based on data from one year prior to the performance period. CMS believes the VM benchmarks are appropriate because they include all PQRS data available including quality data for the Shared Savings Program. CMS does not think it is appropriate to use the Shared Savings Program benchmark because these are calculated using a different methodology.

All-Cause Hospital Readmission Measure: Beginning with the CY 2017 payment adjustment period, CMS proposes to change the reliability policy from a minimum of 20 cases to a minimum of 200 cases for the all-cause hospital readmission measure to be included in the quality composite for the VM.

- CMS proposes to exclude the measure from the quality domain for a group or solo practitioner if there are fewer than 200 cases for the measure during the relevant performance period.
- CMS notes that for groups or solo practitioners that are part of a Shared Savings Program ACO, they would include the all-cause hospital readmission measure as it is calculated for the Shared Savings Program

CMS proposes this change because based on 2012 data, they found that the average reliability for the all-cause hospital readmission measure was below 0.4 for groups with fewer than 200 cases but exceeded 0.4 for groups with 200 or more cases. CMS notes that reliability scores in the 0.4 to 0.7 range are often

considered moderate. CMS also notes that even for those groups where the all-cause hospital readmission measure would be excluded from the quality composite calculations, groups would still continue to have incentives to control readmissions since readmissions also impact the cost composite of the VM.

i. Proposed Expansion of the Informal Inquiry Process to Allow Corrections for the VM

Despite the preclusion of administrative and judicial review, CMS previously indicated in the CY 2023 PFS FR that they believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and established an informal inquiry process at §414.1285. For the CY 2015 payment adjustment period, to align with PQRS, CMS is proposing to expand the established informal inquiry process and establish an initial corrections process that would allow for some limited corrections. CMS notes there would be no administrative or judicial review of the determination resulting from this expanded informal inquiry process.

- CMS is proposing a deadline of January 31, 2015 for a group to request correction of a perceived error made by CMS in the determination of the CY 2015 CV payment adjustment. CMS seeks comment on an alternative deadline of no later than the end of February 2015, the deadline for the PQRS informal review process.
- For the CY 2015 payment adjustment period, CMS proposes to classify a TIN as "average" quality if they determine that they made an error in the calculation of the quality composite. CMS states that they do not anticipate it would be operationally feasible for them to fully evaluate errors with regard to quality measures for the CY 2015 payment adjustment period.
- CMS proposes to recompute a TIN's cost composite if they determine they made an error in the calculation.
- CMS proposes to adjust a TIN's quality tier if they make a correction to a TIN's quality and/or cost composites as a result of this initial corrections process.

CMS proposes to continue the expanded informal inquiry process for the CY 2016 payment adjustment period (CY 2014 performance period). CMS anticipates having the necessary operational infrastructure to support this process and proposes:

- A 30-day period that would start after the release of the QRURs for the applicable period for a group or solo practitioner to request correction of a perceived error in the VM for that payment adjustment period.
- Recompute a TIN's quality composite and/or cost composite when CMS

determines an error was made in the calculation. If CMS lacks the operational infrastructure to allow this recomputation, CMS proposes to continue the CY 2015 proposals.

CMS plans to address in future rulemaking and guidance refinement further development of the expanded informal inquiry process. **CMS requests comments regarding the types of errors, timeline, and other consideration that should be given to both the initial corrections process in the CY 2015 payment adjustment period and the correction process proposed for the CY 2016 payment adjustment period**.

j. Potential Methods to Address NQF Concerns Regarding the Total Per Capita Cost Measures

CMS submitted the total per capita cost measure for NQF endorsement in January 2013. In the final voting in September 30, 2013, the NQF Cost and Resource Use Committee voted against the measure (12 in support and 13 in opposition). CMS is proposing to address two of the concerns: (1) they propose modifications to the two-step attribution methodology and (2) they propose to reverse the current exclusion of certain Medicare beneficiaries during the performance period. CMS proposes applying these changes beginning with the CY 2017 payment adjustment period for the VM. The proposals would apply to all five of the total per capita cost measures.

Attribution Methodology: The attribution methodology finalized in the CY 2013 PFS FR includes a "pre-step" that identifies a pool of assignable beneficiaries that have at least one primary care service furnished by a physician in the group (CMS notes that the "pre-step" was included in the Shared Savings Program assignment methodology to comply with a statutory requirement.) CMS proposes to remove the "pre-step". CMS notes that removing this would streamline the attribution process and ensure that beneficiaries can be assigned to group practices made up of nonphysician eligible professionals. This proposed change would affect all five of the total per capita cost measures and the claims-based quality measures.

Step 1 of the attribution methodology assigns beneficiaries to the group practice with a plurality of primary care services (as measured by allow charges) rendered by primary care physicians in the group (primary care physicians include family practice, internal medicine, general practice, and geriatric medicine). If a beneficiary is not assigned under Step 1, CMS proceeds to Step 2, where beneficiaries are assigned to the group practice whose affiliated non-primary care physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) together provide the plurality of primary care services, as at least one primary care service was provided by a non-primary care physician in the group. NQF members were concerned that primary care services often are provided by NPs, PAs, and CNSs. CMS agrees

and proposes to move NPs, PAs, and CNSs from Step 2 to Step 1 of the attribution methodology.

In summary, CMS proposes:

- Removing the "pre-step"
- Step 1 of the attribution rule would be to assign beneficiaries to the group who had a plurality of primary care services (measured by allowed charges) rendered by primary care physicians, NPs, PAs, or CNS in the group
- Step 2 would assign beneficiaries to the group practice whose affiliated non-primary care physicians provided the plurality of primary care services

For groups and solo practitioner participating in the Shared Savings Program, CMS would continue to use the methodology used by the Shared Savings Program to attribute beneficiaries for quality and cost measures in the VM.

Exclusion of Certain Beneficiaries: NQF members raised concerns that end-of-life costs were not being used for the total per capita cost measure. CMS proposes to include certain part-year Medicare FFS in all five of the total per capita costs. CMS believes the proposed change would provide a more complete assessment of end of life costs associated with a physician group during the year. CMS also proposes including Medicare FFS beneficiaries who are newly enrolled in Medicare during the performance period and enrolled in both Part A and Part B.

CMS proposes to continue to exclude other part-year beneficiaries: those who spend part of the performance period in a Part C plan and those enrolled in Part A or Part B only for part of the performance period and both Part A and Part B for the remainder of the performance period.

CMS notes they are not addressing other concerns about the total per capita cost measures raised by NQF. CMS is deferring the issue of socioeconomic status until after NQF finalizes its guidance regarding risk adjustment for resource use measures. CMS is also not proposing to include Part D data in these measures due to the complexity of this issue. **CMS requests comments on suggested methods for including Part D data in these measures.**

k. Discussion Regarding Treatment of Hospital-Based Physicians

CMS is considering including or allowing groups that include hospital-based physicians or solo practitioner who are hospital-based to elect the inclusion of the Hospital Value-Based Purchasing (VBP) Program performance in their VM calculation. CMS notes that groups could elect to include hospital performance in their VM for a payment adjustment period based on the hospital's historic VBP Program performance which would be known to the TIIN at the time of

election. CMS note any change would be through future notice and comment rulemaking.

CMS requests comments related to this issue including:

- How to identify groups or solo practitioners that would be able to include the VBP in their VM. One option CMS considers is to allow a group to attest that it is composed primarily of hospital-based physicians. Another option is for CMS to specify criteria that a TIN would have to satisfy to have the VBP data as an option. CMS requests comment on the appropriate methodology to identify hospital-based groups and solo practitioners for this purpose.

- The appropriate methodology to determine which hospital or hospital's performance would apply to a given TIN. CMS could base this determination on the plurality of services provided by a TIN or attribute hospital performance to a TIN that provided some threshold of its hospital-based services at that hospital, such as at least 30 percent. CMS seeks comments about other alternatives to address this issue.

- How to determine what part of the hospital's Total Performance Score (TPS) to include in the VM, including how to consider the varied performance periods on measures included in the Hospital VBP Program. CMS also discusses three options for including Hospital VBP performance in the VM: (1) Include the entire TPS in the cost composite; (2) Include the Efficiency and Cost Reduction domain score in the cost composite and include all or some subset of the other domain scores in the quality composite (the option CMS considers to be the most appropriate); and (3) Include some subset of the measures in the cost and quality composites. CMS seeks comments on the approaches discussed and other possible alternatives.

- How to incorporate the portion of the TPS included in the VM into the quality and cost composite scores. CMS discusses how to create a standardized score at the TPS level, the domain level, or the individual measure level which could be weighted into the cost composite for the VM. CMS seeks comments on this methodology and alternative approaches.

I. Regulatory Impact Analysis

CMS notes that the proposed changes in the VM discussed in this proposed rule would not impact the CY 2015 physician payments under the PFS.

CMS has not completed the analysis of the impact of the VM in CY 2015 on physicians in groups with 100 or more eligible professionals based on their performance in CY 2013. CMS presents estimates based on CY 2012 claims data used to produce the 2012 QRURs. Using this data, CMS cannot determine which groups would fall into Category 1 and Category 2. Based on simulation of the 1,032 groups with 100 or more eligible professionals for which CMS produced a 2012 QRUR and for which CMS can calculate quality or cost composite, CMS determined the vast majority of groups (81.0 percent) are in the average quality and average cost tiers (this includes groups missing either the quality or cost composite score and are assigned to average quality or average cost). CMS reports the simulation found that approximately 8 percent of groups are in tiers that would receive an upward adjustment and approximately 10.4 percent of groups are in tiers that would receive a downward adjustment. Table 65, reproduced below, provides additional information.

TABLE 65: Simulated Distribution Using 2012 Data of Quality and Cost Tiers for Groups with 100 or More Eligible Professionals for Which a Quality or Cost Composite Score Could Be Calculated (1,032 Groups)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	0.5%	3.3%	0.7%
Average Cost	4.4%	81.0%	4.0%
High Cost	3.6%	2.4%	0.2%

In the CY 2015 FR, CMS plans to present the actual number of groups and physicians that will be subject to the VM in CY 2015.

5. Physician Feedback Program

CMS plans in late summer, to disseminate QRURs based on CY 2013 data to all physicians. CMs notes these reports will contain performance on the quality and cost measures used to score the cost and quality composites for the VM.

a. Episode Costs and Supplemental QRURs

Section 1848(n)(9)(A) of the Act requires the Secretary to develop an episode grouper and include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient in a defined time period and are captured by claims data. An episode grouper organizes administrative

claims data into episodes.

In the proposed rule, CMS discusses the status of the development and implementation for both acute and chronic episodes, including attribution rules, risk-adjustment methodology, and relevant information included in Supplemental QRURs. CMS notes that they intend to broaden the range of conditions that addressed by episode grouping, such as measures adapted from the Hospital VBP Program.

CMS also discusses how to align episode measures with clinical quality measures included in PQRS and how to align episode measures across provider settings. In the FY 2015 IPPS PR (79 FR 28122 through 28124), CMS discussed six clinical episode-based condition-specific measures for hospitals; CMS also adapted these measures for use in the 2012 Supplemental QRURs. These measures included: (1) kidney/urinary tract infection; (2) cellulitis; (3) gastrointestinal hemorrhage; (4) hip replacement, (5) knee replacement/revision; and (6) lumbar spine fusion/refusion. Further details about these measures and related issues can be found in "Detailed Methods of the 2012 Medical Group Practice Supplemental Quality and Resource Use Reports (QRURS)" at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html. CMS is considering whether to propose their inclusion in the VM through future rulemaking.

CMS continues to seek stakeholder input. They are considering adding episode-based payment measures to the VM through future rulemaking for 12 episode subtypes, or some subset of episode subtypes, of the selected respiratory and selected hear conditions that have appeared in both the 2011 and 2012 Supplemental QRURs. These 12 episode subtypes include: pneumonia (all), pneumonia without an inpatient hospitalization, pneumonia with an inpatient hospitalization, acute myocardial infarction (now called acute coronary syndrome or ACS), ACS without percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG), ACS with PCI, ACS with CABG, coronary artery disease (now called ischemic heart disease or IHD), IHD without ACS, IHD with ACS, CABG without preceding ACS, and PCI without preceding ACS. CMS is also considering proposing to add hospital episode-based payment measures to the VM.

CMS requests comment on the specifications included on the Website and the construction of the episode-based payment measures they are considering.

b. Future Plans for Physician Feedback Reports
CMS will again solicit feedback from physicians after QRURs are released later this summer.

TABLE 56: Summary of Proposed Policies for Groups and Solo Practitioners with Shared Savings Program Participation Changes
(In the table, CMS uses TIN A and ACO 1 and ACO 2 as examples).

Scenario	**TIN's Status During the Performance Period (for example, CY 2015)**	**TIN's Status During the Payment Adjustment Period (for example, CY 2017)**	**TIN's Quality Composite for the Payment Adjustment Period (for example, CY 2017)**	**TIN's Cost Composite for the Payment Adjustment Period (for example, CY 2017)**
a. Continued ACO participation - TIN A participates in ACO 1 during both the performance and payment adjustment periods	TIN A is part of ACO 1	TIN A is part of ACO 1	Based on ACO 1's quality data from the performance period (for example, CY 2015	Average cost
b. Joining an existing ACO and not from another ACO - TIN A was not part of any ACO during the performance period, but participates in ACO 1 during the payment adjustment period (ACO 1 existed in the performance period) OR Joining an existing ACO from another ACO - TIN A participated in ACO 2 during the performance period, but is part of ACO 1 during the payment adjustment period (ACO 1 existed in the performance period)	TIN A is not part of any ACO and ACO 1 exists OR TIN A is not part of ACO 2 and ACO 1 exists	TIN A is part of ACO 1	Based on ACO 1's quality data from the performance period (for example, CY2015	Average cost

c. Joining a new ACO as a new TIN – TIN A participates in ACO1 during the payment adjustment period (ACO 1 and TIN A did not exist in the performance period) OR Joining a new ACO and not from another ACO - TIN A was not part of any ACO during the performance period, but participates in ACO 1 during the payment adjustment period (ACO1 did not exist in the performance period) OR Joining a new ACO from another ACO – TIN A participated in ACO 2 during the performance period, but is part of ACO 1 during the payment adjustment period (ACO 1 did not exist in the performance period)	TIN A and ACO 1 did not exist OR TIN A is not part of any ACO and ACO 1 did not exist OR TIN A is part of ACO 2 and ACO 1 did not exist	TIN A is part of ACO 1	Average quality	Average cost
d. Dropping out of an ACO – TIN A participated in ACO 1 during the performance period, but is not part of any ACO during the payment adjustment period	TIN A is part of ACO 1	TIN A is not part of any ACO	Average quality	Based on TIN A's cost data for the performance period using the quality- tiering methodology

TABLE 57: Summary of Proposed Policies for Groups and Solo Practitioners with Pioneer ACO Model, CPC Initiative, or Other Similar Innovation Center Model or CMS Initiative Participation Changes
(CMS uses TIN A as an example).

Scenario	TIN's Status During the Performance Period (for example, CY 2015)	TIN's Status During the Payment Adjustment Period (for example, CY 2017)	TIN's Quality Composite for the Payment Adjustment Period (for example, CY 2017)	TIN's Cost Composite for the Payment Adjustment Period (for example, CY2017)
a. Scenario 1: TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period, but does not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (some or all of the eligible professionals in TIN A participate in the Pioneer ACO Model or CPC Initiative) AND TIN A registers for PQRS GPRO for the performance period	TIN A is part of the Pioneer ACO Model or CPC Initiative	TIN A is not part of the Shared Savings Program or other similar Innovation Center models or CMS initiatives	If TIN A satisfactorily reports under PQRS GPRO for the performance period: Based on TIN A's PQRS GPRO data If TIN A does not satisfactorily report under PQRS GPRO for the performance period: TIN A falls in Category 2 and a -4.0 percent VM is applied to the TIN in the payment adjustment period	If TIN A satisfactorily reports under PQRS GPRO for the performance period: Based on TIN A's cost data for the performance period using the quality-tiering methodology

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

a. Scenario 3: TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period, but does not participate in the Shared Savings Program or other similar Innovation Center models or CMS initiatives during the payment adjustment period (all eligible professionals in TIN A participate in the Pioneer ACO Model or CPC Initiative) AND For the performance period: TIN A does not report under PQRS GPRO; TIN A reports quality data to the Pioneer ACO Model or the CPC Initiative	TIN A is part of the Pioneer ACO Model or CPC Initiative	TIN A is not part of the Shared Savings Program or other similar Innovation Center models or CMS initiatives	If TIN A successfully reports quality data to the Pioneer ACO Model or CPC Initiative for the performance period: Average quality If TIN A does not successfully report quality data to the Pioneer ACO Model or CPC Initiative for the performance period: TIN A falls in Category 2 and a -4.0 percent VM is applied to the TIN in the payment adjustment period	If TIN A successfully reports quality data to the Pioneer ACO Model or CPC Initiative for the performance period: Based on TIN A's cost data for the performance period using the quality-tiering methodology

b. TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period and participates in other similar Innovation Center models or CMS initiatives during the payment adjustment period (but not the Shared Savings Program)	TIN A is part of the Pioneer ACO Model or CPC Initiative	TIN A is part of other similar Innovation Center models or CMS initiatives (but not the Shared Savings Program)	Based on Scenarios 1-3	Average cost
c. TIN A participates in the Pioneer ACO Model or the CPC Initiative during the performance period and participates in an ACO under the Shared Savings Program during the payment adjustment period	TIN A is part of the Pioneer ACO Model or CPC Initiative	TIN A is part of an ACO under the Shared Savings Program	Based on the Shared Savings Program ACO's quality data for the performance period If the ACO did not exist in the performance period: Average quality	Average cost

IV. Regulatory Impact Analysis

A. RVU Impacts

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, CMS makes adjustments to preserve budget neutrality.

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for CY 2014 with proposed payment rates for CY 2015 using CY 2013 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that 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.

CMS notes that the PAMA has replaced the reduction in the PFS update that would otherwise occur (based on the SGR methodology) on January 1, 2015 with a zero percent update from January 1, 2015 to March 31, 2015. This results in a CF for this period of $35.7977 based upon the zero percent update and the adjustments necessary to maintain budget neutrality. CMS estimates of the impacts in this proposed rule are based upon this CF being applicable throughout the year.

In the absence of further Congressional action, CMS note that the applicable update for the remainder of the year (April 1, 2015 through December 31, 2015) will be based on the statutory SGR formula and the CF will be adjusted accordingly. The most recent estimates of the SGR and physician update for CY 2015 can be found on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/

Table 60 of the proposed rule (included at the end of this section) shows the payment impact on PFS services. The table shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).

CY 2015 PFS Impact Discussion

The most widespread specialty impacts of the RVU changes are generally related to several factors:

1. Changes in work RVU impacts are almost entirely attributable to payment for CCM services. Payment for this service at the proposed rate is expected to result in modest payment increases for family practice, internal medicine, and geriatrics.

2. Changes in PE RVUs are generally related to two CMS proposals. CMS proposal to implement the RUC recommendation regarding the film-to-digital migration of imaging inputs negatively impacts portable x-ray suppliers, diagnostic testing facilities, and interventional radiology. CMS proposal to treat treatment vaults as indirect PE rather than direct PEs negatively impacts radiation oncology and radiation treatment centers.

3. Changes in MP RVUs are primarily attributable to proposed changes as part of the CMS statutorily required review of MP RVUs every five years. CMS highlights, in particular, the negative impacts on the specialties of ophthalmology (-2 percent) and optometry (-1 percent). CMS notes the calculation error it had made in calculating the MP RVUs for theses codes in its last 5-year review, which had resulted in higher MP RVUs than if the calculations had been done correctly.

Column F of Table 60 shows the estimated CY 2015 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. These impacts range from an increase of 3 percent for independent laboratory and an increase of 2 percent for family practice and internal medicine to a decrease of 3 percent for portable x-ray supplier, a decrease of 4 percent for radiation oncology, and a decrease of 8 percent for radiation therapy centers.

Table 61 (Impact of Proposed Rule on CY 2015 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the proposed changes. CMS shows the change in both facility rates and nonfacility rates for these codes.

B. Impacts of Other Proposals

CMS believes that many of the other provisions in this proposed rule would have a negligible or insignificant cost impact on the Medicare program, or one the agency is unable to quantify at this time. The expected impacts of some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary.

Table 60 shows only the payment impact on PFS services. The payment impact on PFS services are based upon a CF of $35.7977 and does not include the effects of the change in the CF scheduled to occur on April 1, 2015 under current law.

TABLE 60: CY 2015 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty*

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
TOTAL	$87,374	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	$215	0%	0%	0%	0%
ANESTHESIOLOGY	$1,979	0%	0%	0%	0%
AUDIOLOGIST	$60	0%	0%	-1%	-1%
CARDIAC SURGERY	$351	0%	0%	-1%	-1%
CARDIOLOGY	$6,420	0%	0%	0%	1%
CHIROPRACTOR	$803	0%	0%	-1%	-1%
CLINICAL PSYCHOLOGIST	$695	0%	-1%	0%	-1%
CLINICAL SOCIAL WORKER	$514	0%	-1%	0%	-1%
COLON AND RECTAL SURGERY	$158	0%	0%	0%	0%
CRITICAL CARE	$285	0%	0%	0%	1%
DERMATOLOGY	$3,162	0%	0%	0%	0%
DIAGNOSTIC TESTING FACILITY	$705	0%	-2%	0%	-2%
EMERGENCY MEDICINE	$3,024	0%	0%	1%	1%
ENDOCRINOLOGY	$455	0%	0%	0%	0%
FAMILY PRACTICE	$6,061	1%	1%	0%	2%
GASTROENTEROLOGY	$1,875	0%	0%	0%	0%
GENERAL PRACTICE	$498	0%	0%	0%	0%
GENERAL SURGERY	$2,222	0%	0%	0%	0%
GERIATRICS	$224	1%	1%	0%	1%
HAND SURGERY	$159	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	$1,803	0%	1%	0%	1%
INDEPENDENT LABORATORY	$703	0%	3%	0%	3%
INFECTIOUS DISEASE	$647	0%	0%	0%	1%
INTERNAL MEDICINE	$11,026	1%	1%	0%	2%
INTERVENTIONAL PAIN MGMT	$672	0%	1%	0%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
INTERVENTIONAL RADIOLOGY	$270	0%	-1%	0%	-1%
MULTISPECIALTY CLINIC/OTHER	$83	0%	0%	0%	1%
NEPHROLOGY	$2,167	0%	0%	0%	0%
NEUROLOGY	$1,502	0%	0%	0%	0%
NEUROSURGERY	$733	0%	0%	1%	1%
NUCLEAR MEDICINE	$48	0%	0%	0%	1%
NURSE ANES / ANES ASST	$1,177	0%	0%	0%	0%
NURSE PRACTITIONER	$2,201	0%	0%	0%	1%
OBSTETRICS/GYNECOLOGY	$690	0%	0%	0%	0%
OPHTHALMOLOGY	$5,663	0%	0%	-2%	-2%
OPTOMETRY	$1,152	0%	1%	-1%	0%
ORAL/MAXILLOFACIAL SURGERY	$44	0%	0%	0%	0%
ORTHOPEDIC SURGERY	$3,649	0%	0%	0%	0%
OTHER	$27	0%	0%	-1%	-1%
OTOLARNGOLOGY	$1,167	0%	0%	0%	0%
PATHOLOGY	$1,067	0%	1%	0%	1%
PEDIATRICS	$58	0%	0%	0%	0%
PHYSICAL MEDICINE	$998	0%	0%	0%	0%
PHYSICAL/OCCUPATIONAL THERAPY	$2,806	0%	0%	1%	1%
PHYSICIAN ASSISTANT	$1,553	0%	0%	0%	1%
PLASTIC SURGERY	$368	0%	0%	-1%	0%
PODIATRY	$1,979	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$109	0%	-3%	0%	-3%
PSYCHIATRY	$1,330	0%	0%	0%	0%
PULMONARY DISEASE	$1,784	0%	0%	0%	0%
RADIATION ONCOLOGY	$1,796	0%	-4%	0%	-4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
RADIATION THERAPY CENTERS	$60	0%	-8%	0%	-8%
RADIOLOGY	$4,497	0%	-1%	0%	-2%
RHEUMATOLOGY	$538	0%	0%	0%	0%
THORACIC SURGERY	$340	0%	0%	0%	0%
UROLOGY	$1,829	0%	0%	0%	0%
VASCULAR SURGERY	$970	0%	0%	0%	1%

*Table 60 shows only the payment impact on PFS services and does not include the effects of the change in the CF scheduled to occur on April 1, 2015 under current law.
** Column F may not equal the sum of columns C, D, and E due to rounding.

The following is an explanation of the information for Table 60:

- Column A (Specialty): The Medicare specialty code as reflected in the physician/supplier enrollment files

- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates. Allowed charges are the Medicare Fee Schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.

- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2015 impact on total allowed charges of the proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2015 impact on total allowed charges of the proposed changes in the PE RVUs.

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

- Column F (Combined Impact): This column shows the estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns