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-FC]

Summary of Final Rule

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I. Introduction and Background

On October 31, 2014, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule with comment period relating to the Medicare physician fee schedule (PFS) for CY 2015 and other revisions to Medicare Part B policies. The final rule is slated for publication in the November 13, 2014 issue of the Federal Register. As noted in the above table of contents, the final rule covers a wide range of issues. Noteworthy provisions and policies this year include the following:

- The third comprehensive review and update of malpractice relative value units (MP RVUs);
- A decision to transform all 10- and 90-day global surgery codes to 0-day global codes and re-value them accordingly, beginning in CY 2017 and CY 2018, respectively, 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;
- 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 in groups with 2 or more eligible professionals and solo practitioners starting in CY 2017 (with a CY 2015 performance period);
- An increase the amount of payment at risk under the VM from 2.0 percent in CY 2016 to 4.0 percent in CY 2017 for physicians in groups of 10 or more eligible professionals (EPs); and
• Expansion of the VM to all nonphysician eligible professions in groups with 2 or more eligible professionals and solo practitioners in CY 2018 (with a probable CY 2016 performance period but the performance period will be formally proposed in the CY 2016 PFS proposed rule).

The final rule also includes matters not addressed in the proposed rule, including CMS responses to comments on CY 2014 interim final values and resource inputs for selected codes, CMS decisions regarding CY 2015 interim final values and resource inputs for new, revised and potentially misvalued codes, the Federally Qualified Health Center (FQHC) prospective payment system, and interim final revisions to the Electronic Health Record (EHR) Incentive Program (pertaining to deadlines for requesting certain hardship exceptions).

These and many other matters are discussed in more detail below.

The provisions of the final rule are effective January 1, 2015, except for the provisions relating to EHR hardship exceptions, which are effective October 31, 2014.

The CY 2015 PFS payment impacts by specialty due to the provisions of the final rule range rather narrowly from an increase of 1 percent for emergency medicine, family practice, hematology/oncology, infectious disease, internal medicine, neurosurgery, nurse practitioners, physical/occupational therapy and radiation therapy centers to a decrease of 2 percent for dermatology, diagnostic testing facilities, ophthalmology and portable x-ray suppliers. These impacts do not take into account the Sustainable Growth Rate (SGR)-related reduction in the PFS conversion factor, currently scheduled to occur on April 1, 2015. Nonetheless, the final rule notes that, absent Congressional intervention, the April-December 2015 conversion factor will be $28.2239, which would be 21.2 percent below the CY 2014 conversion factor ($35.8228) and 22.2 percent below the January-March 2015 conversion factor ($35.8013). Similarly, the April-December 2015 anesthesia conversion factor would be $17.7913, which would be 21.5 percent below the CY 2014 conversion factor ($22.6765) and 21.1 percent below the January-March 2015 conversion factor ($22.5550).

As part of its review of the development of the Medicare physician fee schedule, CMS acknowledges that section 220(i) of the Protecting Access to Medicare Act (PAMA) requires the Secretary to make publicly available the information it considered when establishing the multiple procedure payment reduction policy for the professional component of advanced imaging procedures, but says nothing further about this.

As usual, selected issues in the final rule are open to public comment. These are:  
• Interim final work, practice expense (PE) and malpractice RVUs (including physician time, direct PE inputs, and malpractice crosswalks) for new, revised, potentially misvalued, and certain other CY 2015 HCPCS codes as listed in Addendum C to the final rule;  
• Updates to the list of services subject to the physician self-referral prohibition; and
- **Provisions relating to EHR hardship exceptions.**

*In addition, CMS will accept public nominations for potentially misvalued codes.*

*The comment period on these matters will end on December 30, 2014.*

The addenda to the final 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](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-FC. Readers experiencing problems in accessing the addenda and other documents are advised to contact Donta Henson via e-mail at donta.henson1@cms.hhs.gov.

**II. Provisions of the Final 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 had solicited 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 acknowledges receipt of several comments about variable maintenance costs, which it says it will consider in future rulemaking. However, CMS notes that high-level summary data from informal surveys does not constitute reliable information on this issue and says it would prefer to receive multiple invoices containing equipment prices that are accompanied by maintenance contracts.

CMS had also solicited 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. CMS acknowledges receipt of a comment that addressed how to incorporate usage fees and other per-use equipment costs into its methodology, and several comments that addressed how it should reclassify the anomalous supply inputs removed from the direct PE database, and says it will consider them in future rulemaking.

2. **Changes to Direct PE Inputs for Specific Services**

CMS finalizes without refinement the proposal 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 final 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 finalizes the proposal to include a stretcher for the same length of time as the other equipment items in the moderate sedation package. This change will not be applied retroactively but will be applied to codes being finalized for 2015 as well as interim final codes for 2015.

CMS also finalizes the proposal to accept the RUC recommendation to remove the 30 film supply and equipment items associated with film technology (listed in Table 6 of the final rule) since these are no longer a typical resource input in providing digital imaging services. Table 8 of the final rule lists 38 new codes for which the RUC recommendations for 2015 included film items as practice expense inputs, which CMS has removed. Although the RUC recommended that the Picture Archiving and Communication System (PACS) equipment be included for digital imaging services since these items are now typically used in furnishing these services and although commenters argued that the PACS workstation was significantly more expensive than a desktop computer, CMS finalizes its proposal to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation as a direct expense, saying it still has not received any paid invoices for the PACS; CMS also creates a new equipment item called “desktop computer (proxy for PACS workstation).”

In response to comments requesting that CMS include various items for portable x-ray services (a flat plate receptor/image capture plate, specialized software to process the image, and multiple high definition monitors used by the interpreting radiologist), CMS says that portable x-ray providers use codes that typically describe services furnished using fixed equipment (making it inappropriate to add the image capture plate associated with portable equipment), that high definition monitors are indirect practice expenses, and that it would need more information about the functionality of the software, including whether it is used in furnishing the typical x-ray service.

In the proposed rule, CMS agreed 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). CMS also said it was considering revising the direct PE input database to include task-level clinical labor time information for every code. In the final rule, CMS notes that additional public use files now display the clinical labor tasks for each service period, providing greater transparency and enabling comparisons across codes.

Because it appears that the typical mammography service is furnished using digital technology, CMS had proposed 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. CMS had also proposed to value these CPT codes using the RVUs
prepared previously established for the G-codes. However, CMS has decided to maintain separate codes and payment rates for film and digital mammography for CY 2015 while it considers revaluation of all mammography codes. More specifically, CMS says it will continue to pay for film mammography services “at the 2014 rates” until it revalues the mammography services.

CMS does not finalize the proposed removal of the radiation treatment vault as a direct PE input from 14 radiation treatment procedures, which most commenters opposed. However, CMS says it remains unconvinced that the vault should be considered medical equipment for purposes of the PE methodology, and adds that it intends to further study the issues raised by the vault and how it relates to CMS’ PE methodology. In response to comments, CMS also emphasizes that the pool of indirect PE RVUs is not fixed at the specialty level. Thus, changes in the allocation of indirect PE for particular PFS services (as would have occurred due to removal of the radiation treatment vault) impact the amount of indirect PE allocated to all other PFS services, not just those furnished by specialties that furnish those particular services.

CMS finalizes the proposed correction of two clerical errors. The first corrects the clinical labor type for CPT code 77293 (Respiratory Motion Management Simulation), substituting medical physicist for audiologist. The second moves 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 finalizes its proposal 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 finalizes its proposal to update the price of SD216 (catheter, balloon, esophageal or rectal (graded distension test)) from $217 to $237.50. In contrast, CMS does not finalize its proposal to update the price of SL196 (kit, HER-2/neu DNA Probe) from $105 to $144.50, based on submitted invoices, saying that it has obtained new information suggesting that further study of the price of this item is necessary.

CMS does finalize its plan to update the prices associated with two kits/packs to reflect the addition of supply items by increasing 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) and by increasing 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 finalizes the proposed creation of new direct PE input standard supply package “Imaging w/contrast, standard package” for contrast enhanced imaging, with a
price of $7.06 (rather than the proposed $6.82); the price increase reflects the fact that the supply package includes an IV starter kit, whose price is being increased, as noted above.

CMS does not finalize its proposal 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). CMS says most commenters opposed this proposal on the grounds that the direct PE inputs included in the CPT codes do not reflect the typical resource inputs used in furnishing robotic SRS services. CMS adds that it lacks sufficient information to make a determination about the appropriateness of deleting the G-codes (and paying for all SRS services using the CPT codes) and it will work with stakeholders to identify an alternate approach and reconsider this issue in future rulemaking.

CMS finalizes its proposal 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 also finalizes the proposed price of $4,534.23 for EQ358, based on one invoice, and allocates this equipment item to 95782 for 602 minutes and to 95783 for 647 minutes.

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 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 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 acknowledges receipt of “many thoughtful comments” on whether and how to use the OPPS cost data in establishing PE relative values and says it will consider these as it continues to think about mechanisms to improve the accuracy of PE values.

In order to obtain 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 had proposed 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. CMS finalizes this plan for hospital services. The new 2-digit modifier will be added to the HCPCS annual file as of January 1, 2015, with the label “PO,” the short descriptor “Serv/proc off-campus pbd,” and the long descriptor “Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments.” However, in response to comments
expressing concerns regarding the significant changes to hospitals’ billing systems that will be necessary, CMS adopts a voluntary reporting period for the new HCPCS modifier for one year; thus the new modifier will not be mandatory until January 1, 2016 (rather than the originally proposed January 1, 2015).

With respect to professional claims, CMS agrees with commenters that a place of service (POS) code would allow for the same type of data collection as a modifier and would be less burdensome for practitioners. Thus, CMS will request two new POS codes to replace POS 22 (Hospital Outpatient) through the POS Workgroup, one of which will identify off-campus provider-based departments, and expects that it will take some time for these new codes to be established. CMS adds that more information on the availability of the new POS codes will be forthcoming in subregulatory guidance, but notes that it does not expect the new codes to be available prior to July 1, 2015. CMS also says there will be no voluntary reporting period of the POS codes but argues this is not a problem because the agency intends to give prior notice on the POS coding changes. A CMS fact sheet accompanying the release of the final rule states that the new POS code for services furnished in off-campus provider based departments “will be required for professional claims as soon as it is available, but not before January 1, 2016.”

CMS emphasizes that the new HCPCS modifier and the forthcoming POS code for off-campus provider-based departments should not be reported for services furnished in a “remote location” of a hospital (that is, a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purposes of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider,” including a hospital campus other than the main hospital campus, per regulations at §413.65(a)(2)), in a “satellite facility” (that is one that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital, as described in §412.22(h)), or in emergency departments. The second new POS code will identify outpatient services furnished in on-campus, remote or satellite locations of a hospital, and POS code 23 will be maintained to identify services furnished in an emergency department of a hospital. CMS adds that hospitals and practitioners that have questions about which departments are considered to be off campus provider-based departments should review additional guidance that CCMS releases on this policy and work with the appropriate CMS regional office if individual, specific questions remain.

In response to comments, CMS also says it will take under consideration the suggestion that CMS create a way for hospitals to report their acquisition of physician offices as off-campus provider-based departments through the enrollment process.
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. An interim report, Development of a Model for the Valuation of Work Relative Value Units, is available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban-Interim-Report.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban-Interim-Report.pdf). Urban has begun to collect time data. 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. A description of this project is available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Model.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Model.pdf). CMS anticipates a report by the end of this year and will make the report available on the CMS website.

CMS acknowledges receiving comments regarding both the Urban and Rand project, but notes that they did not solicit any comments about these projects because they did not make any related proposals.

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 41530 (submucosal ablation of the tongue base, radiofrequency). CMS finalizes this code as a potentially misvalued code.

In response to the comment (made by the commenter that originally nominated the code as potentially misvalued) that the RUC had made recommendations for this code and therefore further review was not necessary, CMS notes that the RUC only made PE recommendations and that review of work is also necessary.

- CPT code 99174 (instrument-based ocular screening). CMS finalizes that this code is not a potentially misvalued code because the code in non-covered on the PFS. CMS reiterates their policy of only considering the nomination of active codes that are covered by Medicare at the time of nomination.
CMS acknowledges that they did not identify two codes that they received during the comment period for the CY 2014 FR until after the publication of the proposed rule. CMS notes that they will address the nomination of CPT codes 92227 and 92228 in the proposed rule for CY 2016.

CMS reminds the public and stakeholders that they may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day comment period for the CY 2015 PFS FR. (The FR discusses the supporting documentation requirements.) CMS will evaluate the supporting documentation and in the CY 2016 proposed rule, will publish the list of nominated codes and whether or not they are proposing each nominated code as a potentially misvalued code.

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. The proposed rule listed 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.

CMS finalizes the high expenditure screen as a tool to identify potentially misvalued codes. CMS notes that given the resources that will be required to revalue services with global periods (see section 4), they are not finalizing the codes identified through the high expenditure screen as potentially misvalued and they not responding to specific comments about particular proposed codes. CMS notes that at an unspecified future date they will re-run the high expenditure screen and propose a specific set of codes to be reviewed.

Many commenters disagreed with the high expenditure screen. CMS responds that the screen serves to focus their limited resources on codes where there is a high risk of significant payment distortions. CMS also reminds the reader that their practice to examine the highest PFS expenditure by specialty was begun in response to comments made in the CY 2012 FR that identified codes were only concentrated in certain specialties. In response to comments that E/M services should not be excluded, CMS refers the reader to the CY 2012 FR (76 FR 73060 through 73065). CMS disagrees with comments that they lack the statutory authority for the high expenditure screen; CMS notes that they consider whether the codes meeting the screening criteria impact the relative value of all PFS services due to the budget neutral nature of the PFS. CMS also states that the screen does not assert that codes are misvalued, only that additional examination is required.
2. **Epidural Injection and Fluoroscopic Guidance** (CPT codes 62310, 63211, 63218, 63219, 77001, 77002, 77003)

After considering comments received, CMS finalizes their proposed policies:

- 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 PE inputs for the epidural injection codes includes 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.

Commenters did not object to identifying these codes as potentially misvalued and in general agreed with the proposal to use the 2013 inputs for CY 2015. Several commenters supported the proposal to bundle the image guidance with the epidural procedure while other commenters were concerned that the bundling should be delayed until the services were revalued. CMS does not support delaying bundling because of the significant resources allocated to fluoroscopic guidance within the current injection codes.

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 proposed these codes as potentially misvalued. CMS stated they wanted 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.

CMS finalizes CPT codes 64553 and 64555 as potentially misvalued. Some commenters supported this proposal. In response to a comment opposing this proposal, CMS states the comment did not include any justification for why these codes should not be reviewed.

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).

In response to comments, CMS modifies their proposal and finalizes the following:

- Use CPT codes 77055, 77056, and 77057 to report mammography to Medicare when film technology is used;
- Continue to recognize HCPCS G-codes G0202, G0204, and G0202 but the descriptors will be modified so that they are specific to 2-D mammography;
- Report G0279 or CPT code 77063 when using 3-D mammography;
- Value the CPT codes using the CY 2014 work and PE RVUs; and
- Include CPT codes 77055, 77056 and 77057 on the list of potentially misvalued codes.

In response to the differing opinions about whether or not the mammography codes should be included on the potentially misvalued codes list, CMS states that this disagreement suggest that a review is warranted and that it has been more than 10 years since these services were reviewed. In response to comments about the PE for these services, CMS acknowledges that the PE methodology is not intended to account for the actual cost in furnishing a service. CMS states that the PE methodology is required to account for the relative resources in furnishing these services. CMS is including all mammography codes for RUC review except for the new CPT codes for tomosynthesis since CMS has RUC recommendations for these new codes.

CMS also received differing opinions about whether or not the HCPCS G-codes for mammography should be deleted. CMS decided to continue to use the G-codes because when they reviewed the CPT codes they realized that although the diagnostic mammography CPT codes apply to mammography, whether film or digital is used, the descriptor for the screening mammography CPT code is specific to film. CMS also wants to wait until the RUC has made recommendations for all codes in the mammography family. CMS notes that they expect the CPT Editorial Panel to consider revising the descriptor for the screening mammography CPT code.

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 noted 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. In response to a stakeholder’s suggestion that the
reduction in the RVUs for G0389 did not reflect the resources for this service, CMS proposed the code as a potentially misvalued code.

Many commenters supported CMS’ proposal. After considering comments received, CMS finalizes their proposed policies:
- Include G0389 as a potentially misvalued code; and
- Maintain the 2013 work RVU and use the 2013 PE RVUs for G0389.

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 codes depended on the number of specimens. Based on discussion with stakeholders and reviews of both medical literature and Medicare claims data, CMS proposed to use only one code to report biopsy pathology services.

After considering comments received, CMS finalizes their proposed policies:
- Revise HCPCS code G0416 to report all prostate biopsy pathology services, regardless of the number of specimens;
- Using the existing values for G0416 for CY 2015;
- Include G0416 as a potentially misvalued code for CY 2015; and
- Delete codes G0417, G0418, and G0419.

Many commenters disagreed with CMS’ proposal to consolidate the codes into a single code because pathologists should be reimbursed for the analysis they are required to do based on the number of samples they receive and that these codes should not be considered as misvalued. The RUC and others suggested that CPT code 88305 (Level IV- surgical pathology examination) would be more appropriate and would allow reporting of multiple units. CMS notes that when CPT code 88305 was revalued their was an understanding that prostate biopsies would be billed separately and that billing the CPT code for multiple units for prostate biopsies would account for more resources than appropriate. CMS reiterates that review of Medicare data indicates that G0416 (10 – 20 specimens) represents the majority of all Medicare claims submitted for the 4 G-codes.

7. Obesity Behavioral Group Counseling (GXXX2 and GXXX3)

In response to questions about the coding for obesity behavioral counseling, CMS proposed creating two new codes for the reporting and payment of group behavioral counseling for obesity. The coverage requirements for these services would be the same as described in the National Coverage Determination for Intensive Behavioral Therapy for Obesity.
In response to comments, CMS is creating a single code for group obesity counseling and is crosswalking the work RVU (0.25) and work time (10 minutes) from the Medical Nutrition Therapy group code. The coverage requirements for these services would be the same as described in the National Coverage Determination for Intensive Behavioral Therapy for Obesity. CMS also notes that the services described by the new codes will be billed per beneficiary receiving the service.

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

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. CMS raises several concerns that they believe create substantial barriers to accurately valuing 10- and 90-day global packages relative to other PFS services. To address concerns about the global surgical, CMS proposed the transition of 10- and 90- day global packages into 0-day global packages.

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.

After consideration of comments, CMS is finalizing their proposal to transition and revalue all 10- and 90- day global surgery services to 0-day global periods.
- The transition for 10-day global services will begin in CY 2017.
- The transition for 90-day global services will begin in CY 2018.
- Additional details will be provided during the CY 2016 rulemaking.

CMS notes that they actively seek the analysis and perspective of all affected stakeholders including how to make the transition as seamless as possible for patient care and provider impact. CMS also reiterates that they are committed to bundled payments and will continue to explore the best way to bundle surgical services, including alternatives to the 0-day global surgical bundle.

CMS received many comments supporting the proposal. Several commenters, including medical specialty societies, several health systems and MedPAC supported the proposal. Commenters agreed that the current payment structure for global surgery codes prevents CMS from accurately valuing and paying for these services and may
lead to unwarranted payment disparities. MedPAC supported the proposal and the plan to use the more accurate validations to create more accurate bundles. In general, commenters supporting the proposal also supported the proposed timeframe for the transition.

CMS also received many comments in opposition to the proposal; highlights are summarized below.

Some commenters, including specialty societies urged CMS to postpone finalization of the proposal pending stakeholders efforts to conduct a comprehensive analysis of the effect the proposal would have on surgical care and patients. CMS responds that they share these concerns but given all the concerns about the current global surgery package they do not think delay is warranted.

Some commenters raised concerns that the increased direct and indirect PE and MP RVUs for the E/M services furnished in the global surgical period are not accurately reflected in separately reportable E/M services. In response, CMS states this issue is not a reason to delay or finalize the proposal. CMS also states that they do not agree with commenters that think there should be higher PE and MP values for E/M services furnished in the post-surgical period than for other E/M services.

Several comments noted that the global surgical package includes lower level E/M codes than those generally reported and that the 0-day global package proposal could result in the use of higher level E/M codes. CMS responds that this supports their proposal to revalue these services and they expect physicians to bill the most appropriate E/M code that reflects the service provided. In response to a comment that there might be eventual denial of payment to one or more of the postoperative care providers, CMS acknowledges that there are various models for postoperative care that often include multiple providers and that this is another reason to implement their proposal.

One commenter recommended that CMS establish G-codes for three levels of postoperative visits furnished by the original surgeon or another surgeon with the same board certification and a second set of three level G-codes for postoperative visit furnished by another provider. The RUC provided information that several large hospital-based physician group practices use CPT code 99024 (Postop follow-up visit, normally included in the surgical package) to report each bundled post-operative visit, thus data about E/M visits is available for some Medicare providers and could also be captured from the Medicare denied-claims dataset. The RUC also suggested reviewing Medicare A claims data to determine the length of stay for surgical services furnished in the inpatient hospital setting. CMS states they will consider all these comments as they develop the policy.

There were many comments, both in support and in opposition, to using the “reverse-building block” to revaluing these services. In their comments, MedPAC stated that E/M data collection would be burdensome, time consuming and unnecessary since the
current rate setting methodology assumes a particular number and level of visits. MedPAC suggests CMS should reduce the RVUs for the global services based on the assumptions currently used to pay for these services and if specialty societies or the RUC disagree, they could present evidence that the codes are misvalued to CMS. For codes without accurate post-operative assumptions, MedPAC suggests CMS calculate interim RVUs for these codes based on the average percent reduction for other global codes in the same family. Several commenters agreed with MedPAC. Many commenters, including the RUC, were against the reverse-building block for revaluation citing that the services were not necessarily valued using a building-block methodology. The RUC stated that the amount of post-operative work included in the codes could only be appropriately surveyed and valued by the RUC. CMS states they appreciate all the comments and will continue to explore the appropriate way to valuing these codes.

Most comments expressing concerns about this proposal also urged CMS to delay its implementation. The RUC states that there are over 4,200 services with 10-day or 90-day global periods and thinks the transition should be staggered over many years. CMS notes, however, that the RUC also pointed out that most of these services have low utilization and only 268 (or 6 percent) were performed more than 10,000 times annually based on 2013 Medicare claims data. CMS acknowledges these concerns and that the number of codes to be revalued is much larger than the number of codes that should or can be surveyed. CMS states that they believe there are other options for revaluing some of the global surgery codes as 0-day global packages, particularly those with low volume, and they are willing to work with the RUC to determine appropriate mechanisms for revaluations. CMS notes, however, that they do not believe this required revaluation represents an undue burden between now and the implementation dates. In order to focus efforts on revaluing the global surgery packages, CMS is not asking the RUC to review nearly 100 services that were proposed as potentially misvalued under the high expenditure screen.

CMS urges stakeholders to identify other potential data sources for valuing these services, especially the vast majority of global codes with low volume. CMS also urge stakeholders to help them understand why alternative approaches to revaluation of the global services would require the length of delay that was urged based on the assumption that the RUC survey would be used for all these services.

CMS requests that the CPT Editorial Panel, the RUC and other stakeholders, consider examination of the current coding for surgical services with a focus on the need for establishing and maintaining separate coding and national Medicare RVUs for the many procedures with little utilization in the Medicare population. CMS notes there are over 1,000 10- and 90-day global codes with fewer than 100 annual services in the Medicare database.

In response to many commenters concerns about beneficiaries not returning for necessary follow-up care because of the beneficiary coinsurance for separately billed E/M services, CMS disagrees and notes that the majority of patient encounters requires some degree of beneficiary liability. CMS does acknowledge that surgeons may need
to explain the importance of follow-up care to the overall quality of the patient’s care and outcome. CMS also does not agree with commenters that were concerned that the proposal would result in disjointed or inadequate care. They believe that surgeons will continue to furnish appropriate post-operative care.

In response to comments about concerns about other Medicare payment policies related to surgical procedures, such as multiple procedure payment reductions, CMS notes that there are several hundred 0-day global codes where these payment policies currently apply. CMS again requests input from stakeholders regarding these and other issues that need to be considered in order to implement the transition.

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4. 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 sought 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 states they received many helpful suggestions and intend to address this topic in future notice and comment rulemaking, taking into account the comments they received.

C. Malpractice Relative Value Units (MP RVUs)

For CY 2015, CMS finalizes its proposal to implement the third comprehensive review and update of MP RVUs. The 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 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 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.

The steps for calculating the MP RVUs 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 resource-based MP RVUs equal the total current resource-based MP RVUs.

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.
In the proposed rule, CMS said 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 listed the 35 specialties for which CMS proposed a crosswalk to “similar” specialties. For example, CMS proposed to crosswalk the specialties of hospice and palliative care, optometry, and physical therapy, among others, to allergy and immunology, the specialties of certified nurse midwife and gynecological/oncology to obstetrics/gynecology, and the specialties of nurse practitioner and certified clinical nurse specialist to general practice. In addition, CMS proposed to crosswalk the specialty of certified registered nurse anesthetist to anesthesiology, maxillofacial surgery to plastic and reconstructive surgery, surgical oncology to general surgery, and interventional radiology to diagnostic radiology. In the case of neurosurgery, CMS noted that premium data were available from only 24 states (not the minimum number of 35) and hence CMS proposed 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 added that the surgical premium for neurosurgery is $123,400, and argued that this amount is “similar” to the national average surgical premium amount for neurology ($96,970).

In response to comments, CMS agrees to crosswalk gynecological oncology to general surgery (rather than obstetrics/gynecology), but does not agree to alter the crosswalks for clinical laboratories or interventional pain management. In addition, although the American Medical Association (AMA) and other commenters did not support crosswalking certain non-physician practitioners to allergy/immunology (suggesting that past survey data be used instead), CMS says it would not be appropriate to use survey data for nonphysician specialties and premium data for all other specialties. However, CMS adds that it will explore ways to enhance premium data collection for non-physician practitioners and also other potential measures of central tendency for determining the “indexed” specialty as an alternative to using the premium values of the lowest physician specialty. Two commenters supported the proposal to combine the surgical premium data for neurosurgery and neurology and CMS finalizes this approach.

In the case of step #3 in the MP RVU methodology, 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 (RBMA) 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. In the proposed rule, CMS noted that it continues to classify invasive cardiology services (cardiac catherizations and angioplasties) as surgery for
purposes of assigning specialty-specific risk factors, and also proposed to do the same for injection procedures used in conjunction with cardiac catheterization.

One specialty group noted that the proposed MP RVUs for the TC of some diagnostic services (cardiac catheterization as described by CPT codes 93451 through 93461) increased while the MP RVUs for the PC decreased. In response, CMS notes that the MP RVUs for TC services are generally low and thus a minor increase in the MP RVUs for a TC service could result in a significant percentage change. The RBMA requested that CMS use the recently obtained data reflecting the median "50th percentile" premium data for "umbrella non-physician MP liability" for calculating CY 2015 MP RVUs for TC services. In response, CMS says that using the updated RBMA premium data without further study would be problematic because the updated data reflect only the median umbrella non-physician MP premium, rather than the mean as was used for the 2010 MP RVU update and the proposed 2015 MP RVU update. Nonetheless, CMS adds that it will consider the RBMA’s request and alternatives to the current methodology for calculating the PC risk factor and propose any changes through future rulemaking.

Commenters recommended the addition of certain services to the list of invasive cardiology services (for purposes of assigning risk factors) and CMS agrees to add CPT codes 92961, 92986, 92987, 92990, 92997 and 92998 (but not 92992 or 92993, which are contractor priced). One commenter asked why the MP RVUs for certain cardiac catheterization services (CPT codes 93530, 93531 and 9358) declined and CMS says this is due to a change in the specialty mix of the physicians providing these services. Many commenters asked why the MP RVUs decreased for 4 out of the 6 newly bundled image guided breast biopsy procedures, and CMS says this is due to changes in the risk factors for the related source codes. In response to other comments, CMS says that:

- It will consider an annual collection and review of MP premium data and the rescaling of MP RVUs each year; and
- It can only use MP risk factors by Medicare primary specialty codes (and not all specialties approved by the American Board of Medical Specialties, including the recently approved sub-specialty of Female Pelvic Medicine and Reconstructive Surgery).

With respect to step #4 of the MP RVU methodology, 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. However, in response to comments, CMS agrees to override the dominant specialty from Medicare claims data when that specialty is inconsistent with a specialty that could be reasonable expected to furnish the service. Table 12 of the final rule lists 23 codes where such an override will occur. For example, for CPT code 43350, Surgical opening esophagus, the claims-based dominant specialty of general practice is replaced with the assigned specialty
general surgery. Similarly, for CPT code 74710, X-ray measurement of pelvis, the claims-based dominant specialty of thoracic surgery is replaced by the assigned specialty diagnostic radiology. And for CPT code 96003, Dynamic fine wire emg, the claims-based dominant specialty of cardiology is replaced by the assigned specialty physical therapist/independent practice.

In the regulatory impact analysis provided in the proposed rule, CMS noted 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 said 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. Three commenters asked that this reduction be phased in over 2 years but CMS declines to do so. The same commenters asked that optometry be excluded from calculating the risk factor for ophthalmic surgery (arguing that the MP RVUs for cataract and other ophthalmic surgeries are deflated by inclusion of optometrists, who are only involved during the pre- or post-procedure periods of such surgeries), but CMS says it is appropriate to apply the specialty risk factor(s) of all practitioners participating in and receiving a payment for the surgical procedure for purposes of determining a service level risk factor. Similarly, CMS does not agree with another commenter’s suggestion that assistants at surgery should be excluded from the specialty weighted approach for determining MP RVUs.

For additional information on the methodology for updating the MP RVUs, CMS refers readers to its contractor’s report, “Final Report on the CY 2015 Update of the Malpractice RVUs,” available under the supporting documents section of the CY 2015 PFS final rule.

Although CMS believes that payment rates for anesthesia should reflect relative MP resource costs, including updates to reflect changes over time, it did not propose to update the MP RVUs for anesthesia services at this time because it believed 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. In the proposed rule, CMS said that it intends to include such a proposal in the CY 2016 PFS proposed rule. CMS acknowledges receipt of one comment suggesting that the agency use mean anesthesia MP premiums per provider over a 4- or 5-year period prorated by Medicare utilization to yield the MP expense for anesthesia services, and says it will consider this.

**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 finalizes the proposed changes to 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. CMS will instead 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 will assign a value of 1.0 for the rent index of the PE GPCI. And since CMS has not been able to obtain MP premium data for the Virgin Islands, the existing CY 2015 MP GPCI will not change. Thus, 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 will remain 1.000 but the existing CY 2015 PE GPCI (which reflects a budget neutrality adjustment) will 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 will not apply under current law), the existing CY 2015 work GPCI will fall from 0.998 to 0.975 (-2.30 percent) and the existing CY 2015 PE GPCI will change as noted above for the first quarter of CY 2015. For additional information regarding the changes to the GPCI values for the Virgin Islands, 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 final rule.

CMS acknowledges receipt of many comments that continue to request an increase in the GPCI values for the Puerto Rico payment locality but says that these comments are not within the scope of proposals in the CY 2015 PFS proposed rule and that it has responded to such comments in the past.

E. Medicare Telehealth Services

CMS received several requests in CY 2013 to add various services as Medicare telehealth services effective for CY 2015. CMS finalizes the proposal 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 also finalizes its decision not 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 finalizes the proposal 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) is revised to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS website (at www.cms.gov/telehealth).
CMS acknowledges that many commenters supported expansion of telehealth (e.g., by removing geographic restrictions to include both rural and urban areas and by adding physical and occupational therapists as practitioners who can remotely furnish telehealth services).

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

CMS reminds readers that requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle, and refers readers to the CMS website (at www.cms.gov/telehealth/) for additional information on submitting such requests.

Finally, CMS announces that the telehealth originating fee payment amount for CY 2015 will be $24.83, up 0.8 percent from the comparable CY 2014 fee ($24.63).

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.

1. Process for Establishing Values for New, Revised and Potentially Misvalued Codes

In the proposed rule, CMS discussed potential alternatives to the current approach and proposed a process for establishing values for new, revised, and potentially misvalued codes. The vast majority of commenters supported a process similar to the one proposed. In response to comments, CMS finalizes the following process for establishing values for new, revised, and potentially misvalued codes:

- Use CY 2016 as a transition year.
  - In the PFS proposed rule for CY 2016, CMS will propose values for codes for which they receive RUC recommendations in time for inclusion in the proposed rule. This will also include the two codes delayed from CY 2015 in the CY 2016 rule (CPT codes 92227 and 92228).
  - For codes that CMS does not receive RUC recommendations in time for inclusion in the proposed rule, consistent with current practice, CMS anticipates establishing interim final values for them for CY 2016.

- Begin the new finalized process in CY 2017.
  - For the CY 2017 rulemaking process, CMS would include in the proposed rule proposed values for all services for which they have a RUC recommendation by February 10, 2016. Working with the AMA, CMS
notes this should allow public comment on the proposed values for the vast majority of new, revised, and potentially misvalued codes.

- For codes where CMS does not receive a RUC recommendation by February 10th of a year, CMS would delay revaluing the code for one year and include proposed values in the following year’s rule.
- Use G-codes as necessary to facilitate continued payment for certain services for which CMS receives RUC recommendations too late or for some other reason encounters difficulty in proposing values for revised codes in time for the proposed rule.
- Adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which CMS does not receive RUC recommendations in time to propose values.

- Finalize proposed regulatory changes to §414.24 with the addition of the phrase “For valuations for CY 2017 and beyond,” to paragraph (b) to reflect the implementation of the revised process for all valuations beginning with CY 2017.

Commenters had mixed opinions on when the new process should begin. The AMA, the RUC, and most medical specialties opposed the proposed CY 2016 implementation and requested it be delayed until CY 2017. Commenters said a delay was necessary because considerable work had already been done for the CY 2016 coding cycle and a time delay would allow the CPT Editorial Panel and the RUC time to adjust their agendas and workload to provide more recommendations in time for the proposed rule. Commenters, including the AMA, recommended a later date than the January 15th deadline for recommendations to be considered in the proposed rule. The AMA recommended a deadline of 30 days after the RUC’s January meeting and other commenters suggested an April deadline to include the recommendations from the April RUC meeting. CMS acknowledges the AMA’s efforts and delays the implementation of the finalized process until CY 2017. In response to concerns about the January 15th deadline, CMS states that there is a need to strike a balance that allows CMS adequate time to review recommendations and develop proposals, and allows the RUC as much time as possible to complete its activities. CMS extends the deadline to February 10th and seeks the RUC’s assistance in minimizing the recommendations that CMS receives after the beginning of the year.

The majority of commenters opposed the use of G-codes, citing the administrative burden of using separate codes for Medicare claims. CMS agrees and notes that under the finalized process, the use of G codes should be minimal. In situations where CMS receives the RUC recommendations too late or for some other reason encounters problems developing proposed values for revised code sets, CMS will use G-codes for the purpose of holding over current coding and payment policies. CMS sought alternatives to using G-codes, and the only suggestion offered was to value these codes on an interim final basis. CMS believes that delaying revaluation for one year and allowing a notice and comment period on proposed codes is preferable.
2. Refinement Panel

CMS believed that their proposal to modify the valuation process for new, revised and potentially misvalued codes would limit the number of interim final values which would eliminate the need for the refinement panel process. Thus, CMS proposed eliminating the refinement panel process. In response to comments, CMS is not finalizing their proposal to eliminate the refinement panel.

Commenters expressed concern that the elimination of the refinement panel prevented an appeals process that incorporated advice from contractor medical directors and practicing physicians instead of a review based solely on Agency staff. Commenters also expressed concerns about the current refinement panel process and suggested improvements to the refinement panel. MedPAC suggested a panel with membership limited to those without a financial stake in the process and suggested user fees to provide the resources needed for a refinement panel. In response, CMS notes that the refinement panel is not an appeals process and that its purpose is to give CMS additional information to consider to establish appropriate RVUs. CMS will explore ways to address concerns about the refinement panel process and whether the changes in the process for valuing new, revised and potentially misvalued codes will eliminate the need for a refinement panel.

G. Establishing RVUs for CY 2015

1. Addressing CY 2014 Interim Final RVUs

a. Finalizing CY 2014 Interim Final Work RVUs for CY 2015

Table 14 of the final rule lists the 19 codes reviewed by the 2014 Multi-Specialty Refinement Panel. CMS agrees to change the work value for only one of these 19 codes, CPT 43233, Balloon dilation of esophagus, stomach, and/or upper small bowel using an endoscope, increasing the value from 4.05 to 4.26, the refinement panel median rating. CMS notes that most of the information presented during the last several refinement panel discussions has been duplicative of the information provided to the RUC. CMS adds that if the only information that a commenter has to present is information already considered by the RUC, referral to a refinement panel is not appropriate. The final rule indicates that CMS refused to honor a number of commenter requests for review by the 2014 Multi-Specialty Refinement Panel.

Table 15 of the final rule lists 251 codes with CY 2014 interim final work RVUs for which comments were received and for which CMS is now specifying the CY 2015 work RVU. In many cases, the interim value is simply being finalized without change. This table is followed by a lengthy discussion of code-specific issues, comments and CMS responses. It is beyond the scope of this summary to do justice to this discussion, and thus readers with an interest in any of the codes listed in Table 15 are advised to review the relevant section of the final rule for code-specific details. Note, however, that in the case of interprofessional telephone/Internet consultative services (CPT codes 99446-
CMS says it continues to believe that these codes should have a status indicator of B (Bundled Code) and not qualify for separate payment under Medicare.

b. Finalizing CY 2014 Interim Direct PE RVUs

The final rule discusses the common refinements CMS makes with respect to PE inputs, including those relating to equipment time, standard tasks and minutes for clinical labor tasks, equipment minutes for film equipment inputs, and standard inputs for moderate sedation. For example, CMS believes that highly technical (expensive) equipment would not be kept in a location that does not allow for its maximum utilization and thus it does not count minutes of such equipment time during certain pre- and post-procedure tasks (the CMS assumption is that the equipment is available for use by other patients during these tasks). To provide stakeholders with examples of the types of equipment items that are and are not considered highly technical, the final rule includes Table 16 (reproduced below).

<table>
<thead>
<tr>
<th>Highly Technical</th>
<th>Not Highly Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>CMS Code</td>
</tr>
<tr>
<td>Room, CT</td>
<td>EL007</td>
</tr>
<tr>
<td>Accelerator, 6-18 MV</td>
<td>ER010</td>
</tr>
<tr>
<td>Gamma camera</td>
<td>ER097</td>
</tr>
</tbody>
</table>

Table 17 of the final rule lists 39 codes involving moderate sedation for which a stretcher is being added and a power table removed (if currently included). The affected codes will be considered interim final for CY 2015.

With respect to code-specific direct PE inputs, CMS notes that in future rulemaking, it does not intend to respond to comments that dispute the duplicative nature of inputs unless the commenters specifically explain why the relevant items are not duplicative of the identical items included in a room, kit, pack, or tray.

In addition, Table 19 of the final rule (reproduced below) lists the standard clinical labor tasks to be included in the calculation of time allocated to highly technical equipment (CMS notes that in some cases, some specialized intraservice clinical labor tasks are also included in the equipment time calculations).

<table>
<thead>
<tr>
<th>Clinical Labor Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare room, equipment, supplies</td>
</tr>
<tr>
<td>Prepare and position patient</td>
</tr>
<tr>
<td>Assist physician in performing procedure and/or Acquire images</td>
</tr>
<tr>
<td>Clean room/equipment by physician staff</td>
</tr>
<tr>
<td>Technologist QC’s images in PACS, checking for all images, reformats, and dose page</td>
</tr>
</tbody>
</table>
Table 20 of the final rule (reproduced below) compares the clinical labor tasks and times assumed for film inputs and digital inputs in valuing imaging-related services. Table 21 of the final rule lists 32 codes for which CMS is adjusting clinical labor times due to film-to-digital migration. The affected direct PE inputs will be considered interim final for 2015.

**Table 20: Clinical Labor Tasks Associated with Digital Technology**

<table>
<thead>
<tr>
<th>Service Period</th>
<th>Clinical Labor Task: Film Inputs</th>
<th>Typical Minutes</th>
<th>Clinical Labor Task: Digital Inputs</th>
<th>Typical Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Service</td>
<td>Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD/Retrieve Prior Image for Comparison</td>
<td>4 to 7</td>
<td>Availability of prior images confirmed</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Service</td>
<td>Process Images, complete data sheet, present images and data to the interpreting physician/Process films, hang films and review study with interpreting MD prior to patient discharge</td>
<td>4 to 20</td>
<td>Technologist QC’s images in PACS, checking for all images, reformats, and dose page</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Review examinations with interpreting MD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue</td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

This section of the final rule also includes a discussion of code-specific direct PE input issues, including comments submitted and CMS responses. Below we list the affected codes. Readers with an interest in any of these codes should review the relevant portion of the final rule for code-specific details, which are beyond the scope of this summary.

- Destruction of Premalignant Lesions (CPT codes 17000, 17003, 17004)
- Breast Biopsy (19081-19086, 19281-19288)
- Nasal/Sinus Endoscopy (31237-31238)
- Implantation and Removal of Patient Activated Cardiac Event Recorder (33282, 33284)
- Transcatheter Placement of Intravascular Stent (37236-37237)
- Esophagoscopy (43197-43198)
- Esophagoscopy/Esophagoscopy Gastroscopy Duodenoscopy (43200-43202, 43206, 43215-43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43239, 43245, 43247-43252, 43255, 43270)
- Dilation of Esophagus (43450, 43453)
- Spinal Injections (62310, 62311, 62318, 62319)
- Percutaneous Implantation of Neurostimulator (63650)
k. Chemodenervation (64616, 64642, 64644, 64646, 64647)
l. MRI Brain (70551-70553)
m. MRI Spine (72141, 72142, 72146, 72147, 72149, 72156-72158)
n. Selective Catheter Placement (75726)
o. Radiation Treatment Delivery (77373, 77422, 77423)
p. Hyperthermia (77600)
q. High Dose Rate Brachytherapy (77785-77787)
r. Cytopathology (88112)
s. Duplex Scans (93880, 93882)
t. Electroencephalogram (95816, 95819, 95822)
u. Anogenital Examination with Colposcopic Magnification in Childhood for Suspected Trauma (99170)
v. Immunohistochemistry (HCPCS codes G0461-G0462)

Note that in discussing (q) High Dose Rate Brachytherapy, CMS observes that when a survey of technicians is conducted (which in this case revealed a higher procedure time than the current procedure time) and if the specialty society believes that the code is undervalued, and there is no indication that the survey was flawed, the specialty society should recommend the use of the surveyed procedure times. CMS adds that it believes that surveys of technicians have the potential to be more accurate than those of physicians because the technicians do not have incentives to increase the surveyed times.

c. Finalizing CY 2014 Interim Malpractice Crosswalks for CY 2015

CMS finalizes its CY 2014 interim final malpractice crosswalks. It says it received only 1 comment on the interim final crosswalks, which argued that the crosswalk for certain bronchoscopy codes (CPT codes 43191-43195) does not account for the fact that the bronchoscopy services involve a life-threatening risk to patients and the same is not true for the crosswalk code. However, CMS is not persuaded by the comment and makes no change.

d. Other New, Revised or Potentially Misvalued Codes with CY 2014 Interim Final RVUs Not Specifically Discussed in the CY 2015 Final Rule with Comment Period

For all other new, revised, or potentially misvalued codes with CY 2014 interim final RVUs that are not specifically discussed in the CY 2015 PFS final rule, CMS is finalizing for CY 2015, without modification, the CY 2014 interim final or CY 2014 proposed work RVUs, malpractice crosswalks, and direct PE inputs. Unless otherwise indicated, CMS agreed with the time values recommended by the RUC or the Health Care Professionals Advisory Committee (HCPAC) for all codes addressed in this section.
2. Establishing CY 2015 RVUs

a. Finalizing CY 2015 Proposed RVUs

In the proposed rule, CMS proposed CY work RVUs for several codes. Table 24 in the final rule contains the CY 2015 final work RVUs for these codes.

b. Establishing CY 2015 Interim Final Work RVUs

Table 25 in the final rule contains the CY 2015 interim final work RVUs for all codes for which CMS received RUC recommendations for CY 2015 and G-codes with interim final values for CY 2015. The table provides the CY 2014 work RVUs, the RUC/HCPAC recommended work RVUs, the CY 2015 interim final work RVUs, and whether or not CMS refined the time values recommended by the RUC or HCPAC. These values are subject to public comment.

In this section, CMS also discusses codes for which the CY 2015 interim final work RVUs differ from those recommended by the RUC and codes that did not have RUC recommendations. Highlights of this code-specific CMS discussion are summarized below.

- **Internal Fixation of Rib Fracture (CPT codes 21811, 21812, and 21813)**

  For CY 2015, CPT code 21810 was deleted and replaced with three CPT codes to report internal fixation of rib fracture. The RUC recommended valuing these three codes as 90-day global services. CMS states that because of their concerns about accurately valuing codes as 90-day global services (see section II.B in this summary), they believe these codes should be valued as 0-day global services. CMS is concerned that the RUC recommended too many inpatient and outpatient visits in the post service time. Based on the clinical vignettes for these codes, CMS also believes that it is likely that multiple practitioners would be involved in providing post-operative care. CMS states that all these issues support valuing these codes as 0-day codes.

  CMS used the “reverse building block” methodology to value these codes as 0-day global codes; they subtracted the work RVUs related to the postoperative services from the total work RVUs. CMS also refined the RUC-recommended time by subtracting the time associated with the postoperative visits.

- **Fenestrated Endovascular Repair (FEVAR) Endograft Planning (CPT code 34839)**

  For CY 2015, CPT code 34839 was created to report the planning that occurs prior to the work included in the global period for a FEVAR. Because the RUC survey response was too low to provide an appropriate valuation, the RUC recommended that CMS contractors price this service. CMS notes that they prefer bundling planning services with the underlying service and they assign a PFS procedure status indicator of B (Bundled Code) to CPT code 34839.
- **Illeoscopy, Pouchoscopy, Colonoscopy through Stoma, Flexible Sigmoidoscopy and Colonoscopy (CPT and G codes for lower GI endoscopy codes)**

For CY 2015, the lower GI endoscopy codes were revised and the RUC provided recommendations for these services.

In comments on the proposed rule, commenters suggested that CMS defer the valuation of the new GI code set until 2016 when these codes and their proposed values can be included in the CY PFS 2016 proposed rule which would allow notice and comment prior to the implementation of new values. Stakeholders also suggested that CMS revalue these codes in conjunction with any changes in the reporting and valuation of moderate sedation. CMS agrees with the commenters.

For CY 2015, CMS is maintaining the inputs for these codes at the CY 2014 level (payment rates may change due to budget neutrality adjustments and other policy changes). CMS is also creating G-codes to replace the CY 2014 codes that were deleted (see Table 26 in the final rule). CMS notes that all payment policies that were applicable to the CY 2014 codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes that will not be recognized by Medicare for CY 2015 are denoted with an “I” (Not valid for Medicare purposes) on the Medicare PFS.

- **Radiation Therapy Codes (CPT and G codes)**

As with the lower GI endoscopy codes, CPT revised the radiation therapy code set for CY 2015 and the RUC provided recommendations for these services.

Some stakeholders raised concerns about using interim final values for the vast majority of Medicare services that are furnished by radiation therapy centers and suggested that these code should be included in the CY 2016 PFS proposed rule. CMS agrees with these commenters.

For CY 2015, CMS is maintaining the inputs for these codes at the CY 2014 level (payment rates may change due to budget neutrality adjustments and other policy changes). CMS is also creating G-codes to replace the CY 2014 codes that were deleted (see Table 27 in the final rule). CMS notes that all payment policies that were applicable to the CY 2014 codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes that will not be recognized by Medicare for CY 2015 are denoted with an “I” (Not valid for Medicare purposes) on the Medicare PFS.

CMS also discusses changes in the CPT prefactory text that modifies the services that are appropriately billed with CPT code 77401, a code used to report superficial radiation therapy. Stakeholders are concerned that the prefactory text prohibits billing for codes that were previously frequently billed resulting in reductions in their payments. CMS notes that this change effectively means that CPT code 77401 is now bundled with many other procedures supporting superficial radiation therapy but the RUC did not assess whether this change is accounted for in the value of these procedures. **CMS is interested in information on** whether the new code set combined with the modifications in the prefactory text allows for appropriate reporting of the services.
associated with superficial radiation and whether the payment reflects the relative resources required to furnish superficial radiation therapy services.

- **Breast Tomosynthesis (CPT codes 77061, 77062, and 77603)**
  For CY 2015, CPT created three codes to describe breast tomosynthesis services: 77061 (Digital breast tomo; unilateral), 77062 (Digital breast tomo; bilateral) and 77063 (Screening digital breast tomo, bilateral; list separately in addition to primary procedure code) and the RUC made recommendations for these codes.

  CMS notes that with regard to screening mammography, there is now an add-on CPT code for tomosynthesis; this coding scheme is consistent with the FDA requiring a 2-D mammography when tomosynthesis is used for screening purposes. CMS finalizes that they will recognize code 77063 when tomosynthesis is used in addition to a 2-D mammography and because it does not have an equivalent CY 2014 code, CMS assigns a CY 2015 interim final work RVU of 0.60 (as recommended by the RUC).

  CMS notes that their preference is to value entire families together to avoid rank order anomalies and that the codes for digital mammography are on the potential misvalued code list. Consequently, CMS will not value the new diagnostic mammography tomosynthesis codes until they receive recommendations from the RUC for all mammography services and are assigning a PFS indicator of “I” to CPT codes 77061 and 77062. CMS is creating a new G-code G2079 (Diagnostic digital breast tomosynthesis, unilateral or bilateral; list separately in addition to primary procedure code) and will assign this G code the same inputs as CPT code 77063.

- **Carotid Intima-Media Thickness Ultrasound (CPT code 93895)**
  For CY 2015, this new code describes the work of using carotid ultrasound to measure atherosclerosis and quantify the intima-media thickness. CMS determined this is used only for screening and is assigning a PFS procedure status indicator of N (Noncovered service) to CPT code 93895.

- **Negative Pressure Wound Therapy (CPT codes 97607 and 97608 and HCPCS codes G0456 and G0457)**
  For CY 2015, the two new CPT codes, 97607 and 97608, describe negative pressure wound therapy services with the use of disposable systems and CMS is deleting the corresponding G codes, G0456 and G0457. CMS is contractor pricing these two new CPT codes and the codes will also be designated “Sometimes Therapy” on the CMS Therapy Code List, which is consistent with the policy for the deleted G-codes.

- **Application of Topical Fluoride Varnish (CPT code 99188)**
  CMS notes that since this code describes a service that involves the care of the teeth, it is excluded from Medicare coverage. CMS is assigning a PFS procedure status indicator of “N”.

Prepared by Health Policy Alternatives, Inc.
Advance Care Planning (CPT codes 99497 and 99498)
For CY 2015, CPT created two new codes describing advance care planning services. For CY 2015, CMS is assigning a PFS status indicator of “I” (Not valid for Medicare purposes). CMS notes that they will consider whether to pay for these CPT codes through notice and comment rulemaking.

c. Establishing Interim Final Direct PE RVUs for CY 2015

Table 28, in the final rule, lists the CY 2015 interim final codes with direct PE inputs recommended by the RUC and accepted by CMS without any refinement. Table 31, lists the CY 2015 interim final codes with direct PE inputs recommended by the RUC with CMS refinements. CMS notes that final CY 2015 PFS direct PE inputs is available under downloads for the CY 2015 final rule on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/PhysicianFeeSched/PFS-Federal-Regualtion-Notices.html. The PE RVUs displayed in Addenda B and C reflect the interim final values and policies described in this section. CMS notes that all PE RVUs adopted on an interim final basis are included in Addendum C and are open for comment.

CMS identifies common themes for PE input refinements that are included in Table 31. These themes for refinement include changes in physician time, changes in intraservice work time in the nonfacility setting, changes in the number or level of postoperative office visits in the global period, equipment times (which CMS believes are not used over the full course of a procedure as reflected by clinical labor time), moderate sedation inputs, exceptions to the standard minutes for clinical labor tasks, new supply and equipment items, recommended items that are not direct PE inputs, film-to-digital migration (CMS finalizes removing equipment and supply inputs associated with film technology from the direct PE database and replaces them with “PACS workstation proxy”) and pre-service and post-service tasks for Add-on Codes.

In this section, CMS also discusses codes for which the CY 2015 interim final direct PE differ from those recommended by the RUC. Highlights of this code-specific CMS discussion are summarized below.

- Internal Fixation of Rib Fracture (CPT codes 21811, 21812, and 21813)
CMS states that the new rib fracture codes will be frequently furnished as emergency services. Although the RUC did not include time for the standard pre-service activities it did include time for pre-service activities associated with surgical procedures such as “coordinate pre-surgery services”. CMS reviewed other emergency procedures in the PFS to determine whether similar pre-service clinical labor activities were included. Because this review found inconsistencies, CMS decided not to remove the time allocated for these clinical labor activities from the rib fracture codes. CMS does, however, believe that for emergency procedures none of the pre-service tasks associated with these procedures are typically performed. CMS seeks comments about pre-service tasks and plans to consider the issue in future rulemaking.
- **Breast Tomosynthesis (CPT codes 77061, 77062 and 77063)**
  For these new codes, the RUC recommended creating a new equipment item, “room, breast tomosynthesis” at a price of $667,669 as well as a list of items contained in the room. CMS is not creating this new equipment item but will instead include the individual equipment items they believe are direct costs. CMS does create a new equipment item for digital breast tomosynthesis unit, “DBT unit,” at a price of $381,380. The RUC also recommended a new equipment item, “PACS cache” for digital storage. CMS states that they do not believe digital storage is a direct cost, as it is not individually allocable to an individual patient for a particular service.

- **Hyperbaric Oxygen Therapy (HBOT) (HCPCS code G0277)**
  CMS received a RUC recommendation for CPT code 99183 (Physician and other health care professional attendance and supervision of HBOT) which included a significant increase to the direct PE inputs. CMS notes that currently CPT code 99183 is used for both the professional attendance and supervision and the actual treatment delivery. Stakeholders have pointed out that the PE inputs for this code include more services than what is described in the code.

CMS notes that under the OPPS, the treatment is reported using a separate treatment code, C1300. CMS believes the OPPS approach would be appropriate for the PFS and is creating a G code to report the treatment delivery. CMS will use the same descriptor as C1300, Hyperbolic oxygen under pressure, full body chamber, per 30 minute interval, and will use the RUC-recommended direct PE inputs for 99183 adjusted to align with the 30 minute time interval. CMS also adjusts the units of oxygen to align with the 30 minute G-code.

**Procedures Subject to the Cap on Imaging Codes Defined by Section 5102(b) of the DRA**

Effective January 1, 2015, CMS proposes to add the following new codes to the list of procedures subject to the DRA cap: 76441, 77642, 77085, 77086, 77387, G6001, and G6002. CMS notes that these new codes replace codes deleted for CY 2015 that were subject to the DRA cap and meet the definition of imaging under section 2102(b) of the DRA. **CMS is adding these codes on an interim final basis and these codes are open to public comment.**

**d. Establishing CY 2015 Interim Final Malpractice RVUs**

CMS is assigning malpractice RVUs for CY 2015 new, revised, and potentially misvalued codes by crosswalking to a source code with a similar malpractice risk. For these codes, CMS is accepting all of the RUC-recommended malpractice source code crosswalks. For G-codes created by CMS, CMS is also assigning source code crosswalks to similar codes.

The CY 2015 HCPCS codes and their respective source codes are listed in Table 32 in the final rule. The malpractive RVUs for these services are in Addendum B of this rule.
H. 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.

This new code was designed to pay separately for non-face-to-face care coordination services.

In response to comments, CMS agrees to instead adopt the new CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Comprehensive care plan established, implemented, revised, or monitored).

CMS says this new code appropriately describes CCM services for Medicare beneficiaries and notes commenters’ preference for the “per calendar month” used in the descriptor, instead of the “per 30 days” used in the G-code. In response to comments recommending that CMS adopt more than one CCM code, including two other CPT codes (CPT codes 99487 and 99489), CMS says it will maintain the status indicator “B” (Bundled) for CY 2015 for CPT codes 99487 and 99489 while it continues to evaluate utilization of CCM, including the types of beneficiaries receiving the service and the types of practitioners reporting it. CMS also acknowledges receipt of several comments requesting creation of codes specific to remote patient biometric monitoring (recording vital signs and other physiological data and transmitting real-time data to physicians) but does not directly respond to these comments.

CMS now finalizes proposed new policies or changes to existing policies relating to CCM adopted in the CY 2014 PFS final rule with comment period. First, CMS adopts 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 adopts 20 minutes of clinical labor time as direct PE inputs for the CCM code. Third, CMS will 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 removes 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 also removes 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 adopts 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).

CMS acknowledges that commenters generally believed the proposed valuation for CCM services underestimated the resources involved and supported the higher RUC-recommended values, which assumed 60 minutes of clinical labor (not 20 minutes). However, CMS argues that RUC survey data may be less reliable as the practitioners would have no experience with the new code. Thus, CMS continues to believe that the most appropriate mechanism for determining the appropriate work RVU for CCM is by using the non-face-to-face portion of the lower level TCM code, CPT code 99495. Nonetheless, CMS adds that it intends to evaluate the CCM service closely to assess whether the payment is appropriate for the services being furnished.

In response to comments, CMS notes that it does not have the statutory authority to waive coinsurance for CCM services. However, it emphasizes that it is requiring that providers explain to beneficiaries the cost-sharing obligation but adds that practitioners should explain that a likely benefit of CCM is that it may help them avoid the need for more costly face-to-face services that entail greater cost-sharing.

In the CY 2014 PFS final rule with comment period, CMS announced its intention to adopt standards for CCM services. However, in the CY 2015 PFS proposed rule, CMS did not do so because 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.

CMS did 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. The proposed rule also said 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 meant 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.
In response to comments, CMS agrees that requiring the most recent edition of EHR certification criteria could be an impediment to the broad utilization of the CCM service. Thus, CMS now specifies that the CCM service must be furnished using, at a minimum, the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year (what CMS calls “CCM certified technology”) to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). For CCM payment in CY 2015, this would allow use of EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria to meet the final core capabilities for CCM and to fulfill the CCM scope of service requirements whenever they reference a health or medical record (Table 33 of the final rule summarizes the scope of service elements that refer to a health or medical record). CMS warns, however, that this could mean that a practitioner could use CCM certified technology to provide and be paid for CCM in a given year that will not be sufficient for achieving EHR meaningful use in that same year. CMS also notes that not all meaningful use measures are relevant to the provision of CCM services.

CMS also finalizes the electronic care plan and 24/7 access elements as proposed, but clarifies that to satisfy the care plan scope of service element, practitioners must electronically capture care plan information and make this information available to all care team members furnishing CCM services that are billed by a given practice (counting towards the minimum monthly service time), even when furnishing CCM outside of normal business hours. Practitioners must also electronically share care plan information as appropriate with other providers and practitioners who are furnishing care to the patient. However, CMS emphasizes that it is not requiring that practitioners use a specific electronic technology to meet the requirement for 24/7 access to the care plan or its transmission, only that they use electronic technology other than facsimile. For example, practices could satisfy the 24/7 care plan access requirement through remote access to an EHR, web-based access to a care management application, or web-based access to a health information exchange service that captures and maintains care plan information. Similarly, practitioners could meet the care plan sharing requirement through the use of secure messaging or participation in a health information exchange with other practitioners and providers. CMS also clarifies that practitioners do not have to use any specific content exchange standard in CY 2015 to satisfy the required electronic exchange of a summary care record to support transitions of care. CMS adds that, at least for CY 2015, practitioners should have flexibility in selecting the electronic tool or service they use to transmit beneficiary information in support of care transitions.

In response to various comments, CMS says that practitioners who engage in remote monitoring of patient physiological data of eligible beneficiaries may count the time they spend reviewing the reported data towards the monthly minimum time for billing the CCM code. CMS also disagrees with commenters who did not believe it was necessary to require written beneficiary consent and its documentation in the medical record when furnishing CCM services.
Finally, CMS finalizes a proposed policy under which practitioners participating in the Multi-payer Advanced Primary Care Practice Demonstration or the Comprehensive Primary Care Initiative will 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.

I. Therapy Caps for CY 2015

CMS notes that the existing therapy caps are updated each year based on the MEI and that the cap amounts for CY 2015 will be $1,940, up 0.8 percent from the comparable amounts for CY 2014 ($1,920). CMS also notes that the existing exceptions process for therapy caps and the manual medical review process for claims exceeding a threshold amount of $3,700 both expire on March 31, 2015 under current law.

J. 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 proposed and now finalizes a revision to 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 disagrees with a recommendation to delay implementation of this policy until CY 2016. In response to other comments, CMS says that it does not have the authority to waive coinsurance when a screening colonoscopy leads to removal of a polyp or other abnormal growth or tissue. In such cases, beneficiaries will be responsible for Part B coinsurance for the diagnostic colonoscopy, and similarly, any Part B coinsurance for any covered anesthesia. However, CMS also emphasizes that the statutory waiver of the Part B deductible will apply to the anesthesia services furnished in conjunction with a colorectal cancer screening test even when a polyp or other tissue is removed during the procedure.

CMS notes that anesthesia professionals who furnish a separately payable anesthesia service in conjunction with a colorectal cancer screening test should include the 33 modifier on the claim line with the anesthesia service. In situations that begin as a colorectal cancer screening test, but for which another service such as colonoscopy with polyp removal is actually furnished, the anesthesia professional should report a PT modifier on the claim rather than the 33 modifier.

CMS acknowledges receipt of comments asking the agency to prevent current efforts by Medicare contractors to limit Medicare coverage for anesthesia services furnished during a screening colonoscopy by an anesthesia professional. CMS also notes that
another commenter urged the agency to clarify that the expanded definition of colorectal cancer screening test to include anesthesia services should not be construed to override or preempt existing or planned coverage policies on the appropriate use of these services by Medicare Administrative Contractors. In response, CMS says that the final rule “establishes national policy and takes precedence over any local coverage policy that limits Medicare coverage for anesthesia services furnished during a screening colonoscopy by an anesthesia professional.”

K. Payment of Secondary Interpretation of Images

In the proposed rule, CMS sought 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. For this purpose, CMS posed a number of specific questions.

CMS acknowledges receipt of helpful comments, and notes that most commenters were in agreement that cost savings would be derived from the implementation of a secondary interpretation policy. Many commenters also said they were already furnishing secondary interpretations and would appreciate adoption of a policy that would allow them to receive payment for these services. CMS thanks all the commenters for their input and says that any changes to its current policy on allowing physicians to more routinely bill for secondary interpretation of images will be addressed in future rulemaking.

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

CMS finalizes proposed 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). These changes remove unnecessary distinctions and redundancies within the regulations. For example, §410.60 now refers 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.”

In response to a comment urging CMS to clarify that the revised language would continue to allow therapists in private practice to be employed by physician groups, CMS says that it believes the reference to “group practice” in the revised language is sufficiently broad to encompass a physician group, and “thus permits therapists in private practice to practice as employees of these groups, where permissible under state law.”
M. Payments for 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. In the CY 2015 PFS proposed rule, CMS acknowledged that 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, finalizes the proposal 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.

N. Allowed Expenditures for Physicians’ Services and the Sustainable Growth Rate

1. Medicare Sustainable Growth Rate (SGR)

In the final rule, CMS makes its preliminary estimate of the CY 2015 SGR (-13.7 percent), the first revision to the CY 2014 SGR (-0.8 percent vs. the previous estimate of -16.7 percent), and its final revision to the CY 2013 SGR (1.3 percent vs. the 1.8 percent estimate from the CY 2014 final rule and -19.7 percent estimate from the CY 2013 final rule).

The current estimate for the CY 2015 SGR reflects the following assumptions: 0.7 percent increase in fees for physicians’ services, a 3.9 percent increase in Medicare fee-for-service enrollment, a 0.7 percent increase in real per capita GDP, and -18.1 percent for changes in expenditures due to changes in law or regulations. Values for the statutory factors affecting the SGR calculations for the three years are shown in the table below.

<table>
<thead>
<tr>
<th>Statutory Factors</th>
<th>CY 2015 SGR Calculation</th>
<th>CY 2014 SGR Calculation</th>
<th>CY 2013 SGR Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fees</td>
<td>0.7 percent (1.007)</td>
<td>0.7 percent (1.007)</td>
<td>0.4 percent (1.004)</td>
</tr>
<tr>
<td>FFS Enrollment</td>
<td>3.9 percent (1.039)</td>
<td>0.2 percent (1.002)</td>
<td>0.5 percent (1.005)</td>
</tr>
<tr>
<td>Real Per Capita GDP</td>
<td>0.7 percent (1.007)</td>
<td>0.7 percent (1.007)</td>
<td>0.9 percent (1.009)</td>
</tr>
<tr>
<td>Law and Regulation</td>
<td>-18.1 percent (0.819)</td>
<td>-2.4 percent (0.976)</td>
<td>-0.5 percent (0.995)</td>
</tr>
<tr>
<td>Total</td>
<td>-13.7 percent (0.863)</td>
<td>-0.8 percent (0.992)</td>
<td>1.3 percent (1.013)</td>
</tr>
</tbody>
</table>
2. The Update Adjustment Factor (UAF)

CMS announces that for CY 2015, the update adjustment factor (UAF) is 3.0 percent (1.03).

3. The Percentage Change in the Medicare Economic Index (MEI)

For CY 2015, CMS announces that the increase in the productivity adjusted MEI is 0.8 percent, reflecting an increase in the non-productivity-adjusted MEI of 1.7 percent and a productivity adjustment of 0.9 percent based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity.

4. Physician and Anesthesia Fee Schedule Conversion Factor for CY 2015

Per the final rule, the CY 2015 PFS conversion factor (CF) is for January 1, 2015 through March 31, 2015 is $35.8013, and the CY 2015 PFS CF for April 1, 2015 through December 31, 2015 would be $28.2239 (absent Congressional intervention). Per the final rule, the corresponding national average anesthesia CF is $22.5550 for January 1 through March 31, 2015, and would be $17.7913 for the remainder of CY 2015.

Generally, the PFS CF for a year is calculated by multiplying the previous year’s CF by the PFS update as specified in section 1848(d)(1)(A) of the Act. The temporary fee schedule updates overriding the effect of the SGR in recent years, however, all have specified that subsequent years’ updates will be calculated as if the temporary extensions had not occurred.

CMS estimates that the CY 2015 RVU changes would result in an increase in Medicare physician expenditures of more than $20 million. As required by the budget neutrality provision of section 1848(c)(2)(B)(ii)(II) of the Act, the final rule decreases the CF by 0.06 percent (0.9994) to offset this estimated increase in Medicare physician expenditures. The CY 2015 CF calculations (for both the first three months and the last nine months of the year) are summarized in Table 45 of the final rule, reproduced below (with one apparent error corrected).
Table 45: Calculation of the CY 2015 PFS CF

<table>
<thead>
<tr>
<th></th>
<th>January 1, 2015 through March 31, 2015</th>
<th>April 1, 2015 through December 31, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion Factor in effect in CY 2014</td>
<td>$35.8228</td>
<td>$35.8228</td>
</tr>
<tr>
<td>Update</td>
<td>0.0 percent (1.00)</td>
<td>0.0 percent (1.00)</td>
</tr>
<tr>
<td>CY 2015 RVU Budget Neutrality Adjustment</td>
<td>-0.06 percent (0.9994)</td>
<td>-0.06 percent (0.9994)</td>
</tr>
<tr>
<td>CY 2015 Conversion Factor (1/1/2015 through 3/31/2015)</td>
<td>$35.8013</td>
<td>$35.8013</td>
</tr>
<tr>
<td>Percent Change in Conversion Factor on 4/1/2015 (relative to the CY 2014 CF)</td>
<td>-21.2%</td>
<td>-21.2%</td>
</tr>
<tr>
<td>Percent Change in Update (without budget neutrality adjustment) on 4/1/2015 (relative to the CY 2014 CF)</td>
<td>-20.9%</td>
<td>-20.9%</td>
</tr>
</tbody>
</table>

Table 46 of the final rule provides similar calculations relating to the CY 2015 anesthesia conversion factors but appears to have a number of errors and is not reproduced in this summary. One important difference is that anesthesia services do not have RVUs like other PFS services. Thus, CMS accounts for any necessary RVU adjustments (noted in previous sections of this summary) through an adjustment in the anesthesia conversion factor.

III. Other Provisions of the Final Regulation

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. 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 finalizes the proposal 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 had also proposed 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 proposed 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 noted 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 now finalizes the first part of its proposal but says the second part is not feasible because payment under the ambulance fee schedule is based on ZIP codes and if a ZIP code is predominantly metropolitan but has some rural census tracts, CMS does not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code.

In response to comments, CMS admits that the impact analysis published in the CY 2015 PFS proposed rule presented the impact of the revised OMB delineations only and did not take into account the updated RUCA codes, and rejects commenters’ requests to delay implementation or provide a transition period as a result of the incomplete and potentially misleading analysis in the proposed rule. In any event, CMS now notes that more ZIP codes will change from rural to urban (3,038 or 7.08 percent) than from urban to rural (387 or 0.90 percent); the proposed rule indicated that only 122 ZIP codes would change from rural to urban. The geographic designations for the remaining 92.02 percent of ZIP codes will be unchanged. CMS also confirms that adoption of the revised OMB delineations and the updated RUCA codes will have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas loses its status due to the revised OMB delineations and the updated RUCA codes. CMS notes that Pennsylvania has the most ZIP codes changing from rural to urban, while California has the most ZIP codes changing from urban to rural. Table 47 of the final rule provides a state-by-state assessment of the impact of the revised OMB delineations and updated RUCA codes.
For more detail on the impact of the changes, CMS directs readers to the following files available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html): ZIP codes by state that changed from urban to rural, ZIP codes by state that changed from rural to urban, list of ZIP codes with RUCA code designations, and a complete list of ZIP codes identifying their designation as super rural, rural or urban.

CMS estimates that the adoption of the revised OMB delineations and the updated RUCA codes will have a small fiscal impact on the Medicare program.

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 did not propose 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 finalizes the proposal 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 notes that some commenters expressed concerns about maintaining professional standards and others were concerned about the potential loss of benefits for contracted staff. In response, CMS says that nurses and other health care personnel are expected to maintain their professional standards whether they are employed or contracted by an RHC or FQHC, and that the agency does not regulate employment agreements or benefit packages for individuals working at RHCs and FQHCs.

CMS says this change involves 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.

In the proposed rule, CMS proposed 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. CMS now finalizes this proposal. This means that model participants, and providers and suppliers working under the models operated by such participants, will be required to produce such individually identifiable health information and such other information as the Secretary identifies as being necessary. This will also 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.

As it did in the proposed rule, CMS again 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.

In response to comments, CMS:
- Says that reimbursement for data submission may be considered for future models, but if adopted, any such reimbursement, and any conditions for such reimbursement, would be prominently noted in the solicitation or modification to model agreements;
- Agrees that it is important for potential model participants to understand the data collection requirements before the model begins (to the extent feasible);
- Does not agree that model participants should be given the opportunity to opt out of producing required information, “as this would undermine the evaluation and skew results”;
- Emphasizes that the data collection and submission requirements apply only to model participants, which includes any party that has agreed to participate in, or that receives payment from CMS under, a model CMS is testing;
- Declines to impose a requirement that all participating entities seek patient authorizations to use their records for the purpose of evaluating models being tested and refers such entities to their own legal counsel for advice on whether any form of consent would be required by other applicable law;
- Declines to adopt a requirement to undertake a notice and comment process as part of its determination of what data are necessary for monitoring or evaluation of a model being tested (but says it will strive to provide as much relevant detail as possible about data collection and reporting requirements in any solicitation process);
Respectfully disagrees that sufficient assurances about HIPAA compliance have not been provided and emphasizes that it will only require data that it determines is necessary for evaluation and monitoring of Innovation Center models; and

Accepts recommendations made by commenters to minimize participant burden, seek input from providers, and use independent researchers.

CMS does not anticipate an impact from this policy, noting that participants in Innovation Center models generally receive funding support. CMS adds that in those cases where there is a cost associated with the data reporting, such costs will vary by project, and thus cannot be laid out with specificity in the final rule. Nonetheless, CMS expects such costs to be covered by payments associated with the model test.

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 had proposed 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 have applied to all new draft clinical diagnostic laboratory test LCDs published on or after January 1, 2015. CMS argued that a process that ensures transparency and stakeholder participation can be achieved without utilizing the current LCD process in its entirety. CMS added 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 noted that the LCD manual was originally written about 25 years ago. In developing its proposed expedited LCD process, CMS said 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 pointed 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.

In the final rule, CMS does not finalize any changes to the LCD process and says it will explore the possibility of future notice-and-comment rulemaking on this issue. CMS thanks the numerous public commenters for their time in submitting thoughtful comments on this issue (but provides little detail about these comments) and notes that the comments received have given the agency much to consider prior to moving forward with any changes to the LCD process.
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 finalizes several proposed changes relating to private contracting/opt out. First, a determination relating to the status of opt-out or private contracts will be appealable under the enrollment appeals process currently available for providers and suppliers in part 498. Second, 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 will be appealable under the existing claims appeals procedures in part 405, subpart I.

CMS also finalizes 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.”

CMS anticipates no or minimal impact as a result of the above changes.

In response to comments requesting that physicians and practitioners be allowed to opt out of Medicare indefinitely instead of submitting a new affidavit every 2 years, CMS says the longest interval for which an opt-out can be effective is 2 years and it has no authority to modify this statutory requirement.

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. In the proposed rule, CMS indicated that 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 said it 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, CMS noted that a substitute physician’s NPI is not currently captured on CMS claim forms.

In the proposed rule, CMS solicited comments on the policy for substitute physician billing arrangements for possible use in future rulemaking, and specifically sought input on 12 matters (e.g., whether substitute physicians furnishing services to Medicare beneficiaries should be required to enroll in the Medicare program and whether entities
submitting claims for services furnished by substitute physicians should include the
identity of the substitute physician on the claim form).

In the final rule, CMS acknowledges receipt of “a few comments” on the issues it asked
about (but does not provide any details about these comments) and says it will carefully
consider them in any future rulemaking on this subject.

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 final rule, §403.904(g)(1) has excluded 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) has
required reporting of the marketed name for drugs and biologicals but made reporting
the marketed name of devices or medical supplies optional.

CMS finalizes the proposed elimination of 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. In doing so, CMS does not accept alternative approaches suggested by
comments, such as adopting criteria, such as the Standards for Commercial Support:
Standards to Ensure Independence in CME activities, in order to have payments
provided to physicians at CME events excluded.

In the proposed rule, CMS noted 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 would consider those payments to be excluded
from reporting under §403.904(i)(1), the indirect payment exclusion. However,
commenters pointed out this exclusion presumes that a manufacturer supporting a CME
event would not be able learn the identity of physician speakers at such event during
the reporting year or by the end of the second quarter of the following reporting year but
emphasized that this test was impractical because manufacturers could learn the
identities of physician speakers through brochures, programs and other publications.
This led many commenters to recommend modifying the indirect payment exclusion to
specify that a continuing education indirect payment should be excluded if the
manufacturer did not know the identity of the covered recipient before providing the
payment to a third party, such as a continuing education organization.
In the final rule, CMS clearly states that if an applicable manufacturer or GPO provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer of value in whole or in part to a covered recipient, the applicable manufacturer or GPO is not required to report the payment or other transfer of value. CMS goes on to say that the payment is not reportable “regardless if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year because the payment or other transfer of value did not meet the definition of an indirect payment.” CMS adds that because such payments are not indirect payments, it does not need to create an additional exclusion specific to continuing education indirect payments.

In response to comments, CMS says it did not intend to remove the exclusion regarding subsidized fees provided to physician attendees at continuing education events by manufacturers. CMS adds that it will provide sub-regulatory guidance specifying tuition fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported. However, CMS notes that if a manufacturer does instruct, direct, or otherwise cause the subsidized tuition fee for a continuing education event to go to a specific physician attendee, the payment will not be excluded from reporting.

CMS further proposed 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 said this would make the reporting requirements consistent. In response to comments, CMS finalizes a modified approach under which reporting marketed names for non-covered drugs, devices, biologicals, or medical supplies will continue to be optional (but not for covered products) and under which manufacturers will continue to have an option to report either a device or medical supply marketed name, therapeutic area or product category when reporting research payments.

In addition, CMS finalizes the proposal 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. Commenters agreed that this disaggregation would be useful.

CMS had proposed to begin the data collection requirements affected by the above proposals on January 1, 2015, but the final rule instead adopts a January 1, 2016 compliance date in response to comments.

CMS also finalizes the proposed removal of 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). Copies of the supporting statements and any related forms for this and other paperwork collections addressed in the final rule 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. Paperwork Reduction Act-related comments must be received by December 1, 2014 by the OMB desk officer at OMB, Office of Information and Regulatory Affairs, Attention; CMS Desk Officer, Fax: (202) 395-5806 OR e-mail: OIRA_submission@omb.eop.gov.

J. Physician Compare Website

CMS reviews previously finalized policies for public reporting on Physician Compare and summarizes them in Table 48 of the final rule (reproduced below), which differs in a number of ways from the comparable Table 19 in the proposed rule.

**TABLE 48: Summary of Previously Finalized Policies for Public Reporting on Physician Compare**

<table>
<thead>
<tr>
<th>Data Collection Year</th>
<th>Public Reporting Year</th>
<th>Reporting Mechanism(s)</th>
<th>Quality Measures and Data for Public Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2013</td>
<td>Web Interface (WI), EHR, Registry, Claims</td>
<td>Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx, and participants in the EHR Incentive Program.</td>
</tr>
<tr>
<td>2012</td>
<td>2014</td>
<td>WI</td>
<td>5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices reporting under PQRS GPRO with a minimum sample size of 25 patients and Shared Savings Program ACOs.</td>
</tr>
<tr>
<td>2013</td>
<td>2014</td>
<td>WI, EHR, Registry, Claims</td>
<td>Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx, and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification (MOC) Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.</td>
</tr>
<tr>
<td>2013</td>
<td>Expected to be December 2014</td>
<td>WI</td>
<td>Up to 6 DM and 2 CAD measures collected via the GPRO WI for groups of 25 or more EPs and Shared Savings Program ACOs with a minimum sample size of 20 patients. Will include composites for DM and CAD, if feasible.</td>
</tr>
<tr>
<td>Data Collection Year</td>
<td>Public Reporting Year</td>
<td>Reporting Mechanism(s)</td>
<td>Quality Measures and Data for Public Reporting</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------</td>
<td>------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>2013</td>
<td>Expected to be December 2014</td>
<td>WI</td>
<td>Up to 5 CG-CAHPS summary measures for groups of 100 or more EPs reporting under PQRS GPRO via the WI and up to 6 ACO CAHPS summary measures for Shared Savings Program ACOs.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected to be 2015</td>
<td>WI, EHR, Registry, Claims</td>
<td>Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected to be late 2015</td>
<td>WI, EHR, Registry, Administrative Claims</td>
<td>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 reporting under PQRS GPRO with a minimum sample size of 20 patients. Also, all Shared Savings Program ACO measures are available for public reporting. Include composites for DM and CAD, if feasible.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected to be late 2015</td>
<td>WI, Certified Survey Vendor</td>
<td>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.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected to be late 2015</td>
<td>Registry, EHR, or Claims</td>
<td>A sub-set of 20 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through a Registry, EHR, or claims with a minimum sample size of 20 patients.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected to be late 2015</td>
<td>Registry</td>
<td>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.</td>
</tr>
</tbody>
</table>

CMS notes that some commenters expressed concerns about the accuracy of data on Physician Compare, such as demographic information, specialty classification, and hospital affiliation and that other commenters requested a streamlined process by which professionals can confirm or correct their information in a timely manner. In response, CMS says that the underlying database on Physician Compare is generated from the Provider Enrollment, Chain, and Ownership System (PECOS) and that the most immediate way to address inaccurate PECOS data is by updating information via Internet-based PECOS at [https://pecos.cms.hhs.gov/pecos/login.do](https://pecos.cms.hhs.gov/pecos/login.do). To update information not found in PECOS, such as hospital affiliation and foreign language, CMS directs readers to contact the Physician Compare support team directly at PhysicianCompare@Westat.com, and adds that information regarding how to keep a health professional’s information current can be found at
With respect to the Million Hearts Initiative, CMS notes that it is finalizing the removal of the Cardiovascular Prevention measures group (because 2 of the 6 measures are no longer appropriate) and thus a green check mark indicating support for Million Hearts will be received by eligible professionals who successfully report the remaining 4 individual measures.

In response to comments raising concerns about the validity, reliability, accuracy and comparability of data to be posted on Physician Compare, CMS says it will not publicly post measures that are in their first year and that after a measure’s first year in the program, the agency will evaluate the measure to see if and when it is suitable for public reporting.

CMS then discusses its final policies for public data disclosure on Physician Compare in 2015 and 2016, and summarizes them in Table 49 of the final rule (reproduced below).

**TABLE 49: Summary of Finalized Data for Public Reporting**

<table>
<thead>
<tr>
<th>Data Collection Year</th>
<th>Publication Year</th>
<th>Data Type</th>
<th>Reporting Mechanism</th>
<th>Finalized Proposals Regarding Quality Measures and Data for Public Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>2016</td>
<td>PQRS, PQRS GPRO, EHR, and Million Hearts</td>
<td>Web Interface, EHR, Registry, Claims</td>
<td>Include an indicator for satisfactory reporters under PQRS, participants in the EHR Incentive Program, and EPs who satisfactorily report the individual PQRS Cardiovascular Prevention measures in support of Million Hearts.</td>
</tr>
<tr>
<td>2015</td>
<td>2016</td>
<td>PQRS GPRO &amp; ACO GPRO</td>
<td>Web Interface, EHR, Registry, and Administrative Claims</td>
<td>All 2015 PQRS GPRO measures reported via the Web Interface, EHR, and Registry that 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.</td>
</tr>
<tr>
<td>2015</td>
<td>2016</td>
<td>CAHPS for PQRS &amp; CAHPS for ACOs</td>
<td>CMS-Specified Certified CAHPS Vendor</td>
<td>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.</td>
</tr>
<tr>
<td>2015</td>
<td>2016</td>
<td>PQRS</td>
<td>Registry, EHR, or Claims</td>
<td>All 2015 PQRS measures for individual EPs collected through a Registry, EHR, or claims.</td>
</tr>
<tr>
<td>2015</td>
<td>2016</td>
<td>QCDR data</td>
<td>QCDR</td>
<td>All individual-EP level 2015 QCDR data.</td>
</tr>
</tbody>
</table>
CMS acknowledges that a number of commenters are concerned with “the aggressive timeline” for publicly reporting performance data but says that its “phased approach” to public reporting has allowed the agency to prepare for “this significant expansion.” CMS also assures readers that Physician Compare will only publicly report those measures evaluated to be comparable, reliable, and valid. As noted earlier, CMS also says that it will not publicly report a measure that is newly available for reporting under PQRS (that is, a measure that is in its first year). CMS is also not persuaded by the majority of commenters who believe that a patient threshold of 20 is too low to be statistically valid and finalizes this patient sample threshold.

CMS also finalizes the proposal to include all measures in a downloadable file and limit the measures available on Physician Compare profile pages to those measures that not only meet the requirements of public reporting (such as validity and reliability) but that also are accurately understood and interpreted by consumers as evidenced by consumer testing. In response to one commenter who urged CMS to create Physician Compare downloadable files having a format consistent with that used for Hospital Compare downloadable files, CMS says it will take this recommendation into future consideration.

CMS also notes that there will be a 30-day preview period for quality measures on Physician Compare, and says that 30 days is sufficient time despite commenters’ requests for 60 or 90 days or even longer. Detailed instructions regarding how to preview measure data, the time frame for the measure preview, and directions for how to address any concerns or get additional help during this process will be shared at the start of the preview period with all groups and individuals that have data to preview. If an error is found in the measure display during this 30-day preview, the directions will explain how to contact the Physician Compare team by both phone and e-mail to have concerns addressed. Group practices and EPs will be informed via email when the preview period is going to take place. ACOs will preview their data via their ACO Quality Reports, which will be sent at least 30 days before data are publicly reported.

In the proposed rule, CMS requested 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 also requested comment on creating composites and publishing composite scores in the case of individual practitioners. CMS does not finalize any decisions regarding composite scores at this time and says it will be carefully reviewing all concerns raised and recommendations made (e.g., the need to obtain NQF endorsement of composites) as it continues to evaluate options for including composites in future rulemaking. However, given feedback from some stakeholders indicating such composite scores are desired, CMS adds that it plans to analyze measure data to establish the best possible composites and will consider proposing them in future rulemaking.

For purposes of reporting both group and individual practitioner performance data, CMS proposed 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). However, in response to the many concerns raised by commenters, CMS is not finalizing its proposal at this time. CMS adds that it wants to discuss more thoroughly with stakeholders potential benchmarking methodologies prior to finalizing the proposal.

CMS finalizes its proposal to make available for public reporting on Physician Compare the 12 summary survey CAHPS measures listed in the proposed rule (e.g., Getting Timely Care, Appointments, and Information, Access to Specialists, and Stewardship of Patient Resources) for group practices and ACOs, as appropriate. CMS emphasizes that the CAHPS for PQRS measures are designed to be group-level measures and will not be calculated for individual EPs. CMS adds that prior to deciding the specific CAHPS measures that will be publicly reported on Physician Compare, it will ensure the measures meet the reliability and validity requirements set for public reporting and that the measures are understood and accurately interpreted by consumers. And CMS also notes that it is not adopting any benchmarks for CAHPS for PQRS on Physician Compare.

On the other hand, CMS does not finalize its proposal to publicly report 20 individual EP-level PQRS measures in early 2015, saying that it understands concerns that the 2013 individual EP PQRS data were submitted without an explicit understanding that they would be made public. However, as noted in Table 49 above, because of what CMS describes as the overwhelming consumer demand for individual EP data and the value these data provide to patients, the agency finalizes its proposal to publicly report all 2015 individual EP PQRS measures collected through a Registry, EHR, or claims, except for those measures that are new to PQRS and in their first year.

CMS also finalizes a decision to publish qualified clinical data registry (QCDR) 2015 data on the Physician Compare website in 2016 but will not require these data to be publicly reported on the QCDR websites. CMS adds that publicly reporting the QCDR data on Physician Compare provides a uniform public reporting approach, eliminates the need for health care professionals to verify their data in multiple locations, and provides one, user-friendly website for consumers trying to locate quality data. After this first year of publicly reporting QCDR data, CMS says it will evaluate “if maintaining this policy is most desirable.” In response to comments, CMS also says that QCDR data will only be publicly reported at the individual-EP level.

In the proposed rule, CMS sought comment on posting specialty society measures on Physician Compare as well as on the option of linking from Physician Compare to specialty society websites that publish non-PQRS measures. CMS reports that many commenters supported specialty society measures on Physician Compare or linking to specialty society websites that publish non-PQRS measures. Others opposed this or recommended that CMS maintain control over the public disclosure process to reduce the potential for variable data or consumer confusion. CMS says it will consider all the feedback and may consider addressing specialty society measures and website links on Physician Compare in future rulemaking.
In response to comments considered “beyond the scope” of this rulemaking, CMS:

- Says it understands that availability of PQRS measures may make it difficult for some specialties to report;
- Says it will continue to work to ensure that the language included on Physician Compare helps users understand that there are a number of reasons a physician or other health care professional may not have quality data on the website;
- Notes that performance scores on Physician Compare are displayed visually using 5 stars, with each star representing 20 percentage points;
- Reminds readers that the word “Physician” in Physician Compare is used to be consistent with section 10331 of the ACA, even though the site includes data for non-physicians;
- Acknowledges receipt of suggestions for additional information to publicly report on Physician Compare, such as the Certified Medical Director designation and the Certificate of Added Qualifications in Geriatric Medicine, noting that one important consideration around such recommendations is whether there is a readily available national-level data source; and
- Agrees that Surgical CAHPS data is useful to consumers and says it is exploring how it can incorporate this information into Physician Compare.

Finally, CMS says it anticipates timely submission of a mandated report to Congress on the Physician Compare website, which is due no later than January 1, 2015.

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

The proposed rule primarily focused 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).

In the proposed rule, CMS sought comment on whether, in future years, it should allow for more frequent submissions, such as quarterly or year-round submissions, for PQRS quality measures data submitted under various reporting mechanisms. CMS says many commenters supported this concept, but some of them preferred that the ability to provide more frequent submission of data be optional. CMS adds that it will consider the commenters’ feedback if and when it proposes this policy in future rulemaking.
1. Requirements for the PQRS Reporting Mechanisms

CMS did not propose to make changes to the claims-based reporting mechanism.

For the qualified registry reporting mechanism, CMS had proposed 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 (now listed in Table 52 of the final rule) for which the registry’s participating eligible professionals (EPs) are able to report. This was because CMS was 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). However, in response to comments opposing this proposal, CMS will only require a registry to be able to report on at least 1 cross-cutting measure on behalf of its participating EPs and group practices (as noted later in this summary, individual EPs will only be required to report 1 cross-cutting measure, not the 2 that had been proposed). For the qualified registry reporting mechanism, CMS finalizes the proposal 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).

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 finalizes the proposal to have direct EHRs and EHR data submission vendors comply with CMS Implementation Guides for both the QRDA-1 and QRDA-III data file formats for 2015 and beyond. For 2015 and beyond, CMS had proposed to have the EP or group practice provide the CMS EHR Certification Number of the product used but now says it would be infeasible for CMS to collect this information because it does not have a venue in which to store this information.

With respect to reporting via QCDR, CMS had proposed 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). CMS added 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 proposed 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.”

1 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.
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.”

Given that the majority of commenters opposed this proposal, CMS finalizes a requirement that QCDRs report on at least 2 outcome measures, rather than the proposed 3 (or, in lieu of 2 outcome measures, at least 1 outcome measure and 1 of the following other types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety. Note that CMS has listed patient safety as an additional option beyond the 3 given in the proposed rule. CMS finalizes all of the definitions listed above, claiming it received no comments regarding them. CMS also provides no additional guidance regarding what constitutes each of these types of measures.

For QCDRs, CMS also finalizes the proposal to increase the maximum number of non-PQRS measures that can be reported on behalf of an EP from the current 20 to 30. As it did in the proposed rule, 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. To the extent that further clarification on the distinction between a PQRS and a non-PQRS measure is necessary CMS says it will provide additional guidance at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments-pqrs/index.html.

Beginning in 2015, CMS had also proposed 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 proposed 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 proposed to defer to the QCDR in terms of the method it will use to publicly report the quality measures data. For example, CMS said 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 added that a QCDR would meet the proposed public reporting requirement if the QCDR’s measures data were posted on Physician Compare. CMS also proposed 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.

Although CMS finalizes the above QCDR public reporting requirement, it makes a few important changes. First, CMS agrees with commenters on delaying the public posting of measures information until a measure has been tested for validity and reliability and thus provides an exception for new measures (both PQRS and non-PQRS measures) that are in their first year of reporting by a QCDR under the PQRS. CMS goes on to define a measure being introduced in the PQRS for the first time as the first time a quality measure is either introduced in the PQRS measure set in rulemaking as a new measure for that reporting period or, for non-PQRS measures that can be reported by a QCDR, the first time a QCDR submits a measure (including its measure specifications) for reporting for the PQRS for the first time. CMS adds that to the extent a QCDR first reports on a non-PQRS measure that is already being reported by another QCDR, the agency would consider the measure a measure that is in its first year of reporting for that respective QCDR who is reporting the measure for the first time. Later, CMS states that “quality measure data for a PQRS or non-PQRS measure that is being reported by a QCDR in the PQRS for the first time does not need to be posted for at least the initial year.” CMS also clarifies that it intended to specify a deadline of April 30, not the proposed April 31, which does not exist in the calendar. However, CMS also notes that given concerns from commenters that April 30 does not provide the QCDRs with enough time to accurately post quality measures data, it is extending the deadline by which a QCDR must publicly report quality measures data outside of Physician Compare to the deadline by which Physician Compare posts QCDR quality measures data as shown in Table 49 above. CMS says this means that QCDRs “wishing to publicly report quality measures data outside of Physician Compare must do so in 2016” (not by April 30, 2016).

Beginning in 2015, CMS also proposed 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 finalizes this proposal.

CMS also finalizes the proposal 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 also adopts the proposed extension to the deadline for QCDRs to submit quality measures data calculations to CMS to March 31.

With respect to the Group Practice Reporting Option (GPRO), CMS adopts the proposed, 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 done because CMS believes there is benefit in providing timelier feedback reports. CMS notes that this registration deadline refers to all group practices wishing to participate in the GPRO using any available GPRO reporting mechanism, including the GPRO web interface, registry, EHR and/or CMS-certified survey vendor.

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

The satisfactory reporting criteria for individual EPs for the 2017 PQRS payment adjustment are as follows (changes from the proposed criteria are noted):

**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 1 measure 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. Measures with a 0 performance rate would not be counted.

CMS acknowledges that the majority of commenters opposed the proposal to require 9 measures but argues that it has given the public adequate time to prepare for this. CMS also notes its intention to eliminate the claims-based reporting mechanism in future rulemaking and encourages EPs to use alternative reporting methods to become familiar with reporting mechanisms other than the claims-based one. CMS reduces the number of required cross-cutting measures to 1 (instead of the 2 it originally proposed) but warns that it intends to move towards requiring the reporting of more cross-cutting measures in the future. CMS also says it will consider addition to the cross-cutting measure set in the future so that more professionals that are eligible may be able to participate in the reporting of a core set of measures. In this regard, CMS states that an EP “would not be required to report on the measures contained in the cross-cutting measures set if none of the measures applied to the eligible professional’s practice.”
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. CMS adds that it will post additional clarifying information, including a document explaining the MAV process for 2015, on the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html. CMS also says that the MAV process will allow the agency to determine whether an EP or group practice should have reported on any of the cross-cutting measures specified in Table 52.

With respect to the issue of face-to-face encounters (relevant for reports via claims or qualified registry), CMS says it will 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 will not include telehealth visits as face-to-face encounters for purposes of the cross-cutting-measure reporting requirement. Although the final rule does not provide the specific codes for what CMS defines as a “face-to-face” encounter, CMS says it will provide the codes and any additional guidance on the PQRS website.

3. Satisfactory Participation in a QCDR by Individual EPs

CMS adopts the following criteria for satisfactory QCDR participation for the 2017 PQRS payment adjustment (changes from the proposed rule are noted):

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 2 outcome measures, or, if 2 outcome measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures – resource use, patient experience of care, efficiency/appropriate use or patient safety.
See the discussion in section III.K.1 above regarding the issue of outcome and other measures. As noted there, CMS has reduced the number of required outcome measures (from 3 to 2) and added patient safety as an additional alternative measure type (if 2 outcome measures are not available). However, CMS notes that it intends to increase the number of outcome measures that must be reported in the future.

4. 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 adopts 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 2-99 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 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 contained in the cross-cutting measure set. Measures with a 0 percent performance rate would not be counted.

As is the case for individual EP reporting, CMS reduces the number of required cross-cutting measures to 1 (from the 2 originally proposed). CMS notes that the MAV process does not apply to the application of the cross-cutting measure reporting requirement, as the agency requires that all group practices report on at least 1 cross-cutting measure if an EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter. However, later in the final rule, CMS
appears to contradict itself when it says that “[i]f a group practice reporting on less than 9 measures does not have at least 1 cross-cutting measure applicable to his or her practice, then the group practice would report on as many measures as are our (sic) applicable to his or her practice.” Further, the final rule also states that “the MAV will also allow [CMS] to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52.”

Via EHR Direct Product or EHR Data Submission Vendor

For a group practice of 2-99 EPs, report 9 measures covering at least 3 NQS domains. If a group practice’s direct EHR product or EHR data submission vendor product 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 2 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 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey 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 2 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 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, 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 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 increasing the sample size for groups of 25-99 EPs from 218 to 248 and reducing the sample size for groups of 100 or more from 411 to 248.

For purposes of reporting through the GPRO web interface, CMS finalizes the proposed adoption of a modified beneficiary attribution methodology that differs slightly from the one used under the Medicare Shared Savings Program. This modified methodology is also being finalized 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 will also again require 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, to select a CMS-certified vendor to administer the CAHPS for PQRS survey on their behalf. CMS confirms that beginning in 2015, it will 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 will remain optional for smaller groups but if elected, such groups will also need to pay a CMS-certified survey vendor.

The proposed rule also proposed criteria for satisfactory reporting on individual PQRS quality measures for group practices that participate in the GPRO for the 2018 PQRS payment adjustment and subsequent years. Under this proposal, 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 final rules includes no discussion of this matter.

The final rule also addresses the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS). In response to comments supporting the introduction of S-CAHPS in the PQRS, 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 or 2018 PQRS payment
adjustment” [emphasis added]. As it did in the proposed rule, CMS notes that it would allow the reporting of the S-CAHPS through a QCDR (as a non-PQRS measure).

5. PQRS Quality Measures for 2015 and Beyond

As it did in the proposed rule, CMS 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](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.

Under PQRS, if CMS discovers errors in the most recently updated electronic measure specifications for a certain measure, it uses 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 I-III 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 52 of the final rule lists the 19 cross-cutting measures that CMS adopts for use during 2015 and beyond. In addition to including the 18 measures originally proposed, this table now includes the measure, Diabetes: Hemoglobin A1c Poor Control, in response to comments. This table gives CMS’ response to comments and final decision for each measure and also indicates the available reporting mechanisms, some of which have changed since the proposed rule.

Table 53 of the final rule lists 18 new measures being added to the PQRS measure set for CY 2015 and beyond (either as originally proposed or with modification) and the 8 proposed measures not being finalized. This table includes CMS’ response to comments regarding each of these measures.

Table 54 of the final rule lists 23 current PQRS measures for which a CMS-proposed change in NQS domain change is being finalized and the 1 measure (Unplanned Hospital Readmission within 30 Days of Principal Procedure) for which a proposed domain change is not being finalized.

Table 55 of the final rule lists 50 measures whose proposed deletion from the current PQRS measure set is being finalized and the 23 measures whose proposed deletion is not being finalized. In a number of cases, a measure is being retained because a measure steward has been identified for the measure.

Table 56 of the final rules lists 33 PQRS measures for which CMS-proposed changes to the way in which the measures may be reported beginning in 2015 are finalized, and 28 measures where such proposed changes are not finalized. The latter includes a
number of measures that will continue to be reportable via claims because upon further review, CMS agrees that a significant number of providers that report these measures would be negatively impacted by the removal of the claims-based reporting option.

With respect to measures groups, CMS finalizes the proposed increase in the minimum number of measures from 4 measures to 6, despite several opposing comments. CMS also finalizes the addition of two new measures groups beginning in 2015: the sinusitis measures group and the acute otitis externa measures group. CMS had proposed to remove 6 measures groups and finalizes the removal of the following 4:
- Perioperative care measures group;
- Back pain measures group;
- Cardiovascular prevention measures group; and
- Ischemic vascular disease measures group.

The remaining 2 measures groups proposed for deletion are retained because a new steward has been identified for the measures at risk. These retained measures groups are the following:
- Sleep apnea measures group; and
- Chronic obstructive pulmonary disease measures group.

With respect to removal of the perioperative care measures group, CMS says that while there has been evidence to suggest there may be bias in measuring that improves performance (as asserted by commenters), there is an equal amount of evidence to the contrary that suggests this bias is not impactful. CMS also believes that there are a number of broadly applicable PQRS measures that specialty surgeons can report, notwithstanding commenters’ concern that removal of the perioperative measures might make it difficult for surgeons to participate in PQRS.

Tables 57 through 79 of the final rule specify the 22 measures groups adopted for 2015 and beyond. The tables list the measures included in each measures group, which range from 6 to 10 measures. In the case of the Rheumatoid Arthritis Measures Group, CMS agrees to substitute cross-cutting measure Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up (PQRS #128) and Pain Assessment and Follow-up (PQRS #131) for the two measures originally proposed by CMS, Preventive Care and Screening: Influenza Immunization (PQRS #110) and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (PQRS #226).

With respect to the GPRO web interface, CMS finalizes the proposed removal of 4 of 5 existing measures, removes one additional measure (Diabetes Composite: Optimal Diabetes Care), and retains one measure that had been proposed for removal (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombic). This measure is retained because upon further review CMS determined that the measure does not conflict with updated cholesterol guidelines and because its retention maintains alignment with the Million Hearts program. All these measures and CMS’ response to comments regarding them can be found in Table 79 of the final rule. CMS also finalizes the proposed addition of 4 new measures for GPRO web interface.
reporting, does not finalize the proposed addition of 4 others, and removes one additional measure (Diabetes Composite: Optimal Diabetes Care). This measure is also being removed from the PQRS and Shared Savings Program measure sets. All of these measures and CMS' response to comments regarding them can be found in Table 80 of the final rule. Note that one of the new measures, Depression Remission at Twelve Months, is being designated as pay-for-reporting under the Medicare Shared Savings Program for all 3 years of an ACO’s first agreement period. This is due to concerns regarding the use of the PHQ-9 tool in assessing patients (more specifically, that not all practices now use this tool) and a desire to provide ACOs with time to make necessary adjustments for implementation.

In the proposed rule, CMS acknowledged that it previously misclassified the CAHPS for PQRS survey under the care coordination and communication NQS domain and now finalizes its proposed reclassification under the Person and Caregiver-Centered Experience and Outcomes domain.

6. QCDR Measure Issues

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

CMS finalizes the proposal requiring a QCDR to 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 also finalizes the proposed requirement under which 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, proposed to modify the payment adjustment information review deadline to within 30 days of the release of the feedback reports. However, in response to comments, CMS agrees to extend this
to 60 days following release of the feedback reports. Nonetheless, CMS warns that it reserves the right to propose further changes in this deadline in future rulemaking.

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

- CMS will 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 will only allow resubmission of data that was already previously submitted to CMS.
- CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

In doing so, CMS acknowledges receipt of several comments generally supporting the proposal to allow for resubmission of data.

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 final 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 will range from a low of about $249.3 million to a high of about $466 million. And the total annual cost for the 200 group practices reporting via the web-based interface is estimated at $1.3 million. These estimates are essentially double those contained in the proposed rule, apparently because the estimated labor costs now take both salary and fringe benefits into account.

CMS assumes that a billing clerk will handle the administrative duties associated with PQRS participation (at a mean hourly labor cost of $32) and that a computer analyst will handle duties related to reporting PQRS measures (at a mean hourly labor cost of $82). CMS further estimates that an eligible professional or group practice will spend 5 hours to get ready to participate in PQRS for the first time. CMS’ estimate of administrative costs assumes that a billing clerk will be handling the requisite tasks. 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 will range from 2.25 minutes to 108 minutes. CMS further assumes that a physician will report data for an average of 6 cases per measure, meaning that the total cost of claims-based reporting will range from $18.36 to $885.60,
with the cost to the median practice estimated at $129.60 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 or 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 will 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 will take an EP or group no more than 2 hours.

CMS also estimates that it will 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 $192. 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 $6,478 (the 79 hours is the same as that estimated in the past despite the change in sample size for web-based interface reporting).

CMS does not account for the reporting of CAHPS survey measures via a CMS-certified survey vendor 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 CEHRT products to the most recent version of the electronic specifications for the CQMs, CMS proposed that beginning in CY 2015, EPs would not have to meet this requirement. The majority of commenters supported this proposal and CMS finalizes that beginning in CY 2015, EPs are not required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs.

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 updated electronic measure specifications. CMS finalizes that beginning in CY 2015, if CMS discovers errors in the most recently
updated electronic measure specifications for a certain measure, they will use the
version that immediately preceded the most recent update. CMS notes that with
respect to the measure CMS140v2, Breast Hormonal Therapy for Stage I-IIIIC
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 used CEHRT would satisfy the CQM reporting component of meaningful use for the
EHR Incentive Program. For CY 2015, CMS proposed 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. After consideration of the
comments received, CMS is finalizing the proposal to reduce the required number of
domains for CY 2015 from three to two.

M. Medicare Shared Savings Program

With respect to the Medicare Shared Savings Program involving accountable care
organizations (ACOs), the final rule revisits the current quality performance standard,
adopts changes to the quality measures, and responds to comments on future quality
performance measures. It also modifies the timeframe between updates to the quality
performance benchmarks, establishes an additional incentive to reward ACO quality
improvement, and makes several technical corrections to the regulations in subpart F of
Part 425.

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

In the proposed rule, CMS proposed 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 have involved 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. In the final rule, CMS finalizes the
addition of 8 new measures, the removal of 7 existing measures, and also the removal
of one additional measure not addressed in the proposed rule. The end result is that
ACOs will continue to be evaluated against a total of 33 measures but the number of
measures reported through the CMS web interface will be reduced by 5, thereby
reducing the administrative burden for ACOs.
More specifically, CMS finalizes the addition of the following 8 new measures:

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 will 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;
7. Diabetes Measure for Eye Exam; and
8. Documentation of Current Medications in the Medical Record, which will 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.

With respect to the CAHPS Stewardship of Patient Resources Measure, despite commenters’ concerns about this measure, CMS argues that discussing prescription medicine costs with beneficiaries can lead a clinician to understand whether and how the beneficiary may struggle with payment for medications, a factor that can affect adherence. Further, the measure is already part of the CAHPS survey. However, because this will be a new ACO measure, CMS says it will be pay-for-reporting for the first two reporting periods it is in use for all ACOs, regardless of the phase-in schedule to pay-for-performance, in order to provide time for the development of an appropriate benchmark. After the measure has been used in the program under pay for reporting for two reporting periods, it will be pay-for-reporting for the first performance year of an ACO’s first agreement period and pay-for-performance for the ACO’s second and third performance years.

With respect to the Skilled Nursing Facility Readmission Measure, despite some commenters’ belief that this measure is unnecessary and duplicative since it is an inherent part of the Shared Savings Program that an ACO will be penalized through a reduction in shared savings if it has a high rate of readmissions, CMS believes that including the measure would reinforce the importance of coordinating the care of beneficiaries across hospital and SNF sites of care. Some commenters recommended that CMS use a risk-adjusted, potentially avoidable SNF readmission measure, but CMS says there is not such a measure currently available for use. CMS notes, however, that the SNF 30-day all-cause readmission measure does exclude planned readmissions. After the SNF Readmission Measure has been used in the program under pay for reporting for two reporting periods, the measure will be pay-for-reporting in the first two performance years of an ACO’s first agreement period and will transition to pay-for-performance in the final year of the ACO’s agreement.
Some commenters opposed the addition of the above 3 Unplanned Admissions measures because they lack NQF endorsement. Others supported applying the measures as pay-for-reporting-only since they are still under development, accepted target rates are not available, and the measures are not yet endorsed by NQF. CMS believes the 3 measures are important to promote and assess ACO quality because the relevant chronic conditions are major causes for unplanned admissions and the addition of the measures will support ACOs’ efforts to improve care coordination. CMS says it intends on submitting all 3 measures to NQF for review in the future and it will provide final measure specifications to the public when available (typically in the early part of the performance year). The 3 measures will be added as pay-for-reporting for two performance years. After this time, the measures will be pay-for-reporting for the first two performance years for new ACOs in their first agreement period before transitioning to pay for performance in performance year three.

CMS does not finalize the proposed addition of the following 4 measures:
1. Diabetes Measure for Foot Exam;
2. Coronary Artery Disease: Symptom Management (an assessment of patient activity level and management of angina);
3. Coronary Artery Disease: Beta Blocker Therapy—Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF<40%);
4. 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.

With respect to the above Antiplatelet Therapy measure, CMS says it is instead retaining ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombic (NQF #0068) because it has determined that it does not conflict with clinical guidelines (as originally feared) and because it aligns with the Million Hearts Campaign.

CMS finalizes the proposal to no longer collect data on the following 7 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); and
7. ACO #32, Coronary Artery Disease Composite: Drug Therapy for Lowering LDL Cholesterol (same rationale as for #5 and #6).

As noted earlier, CMS retains one of the measures it had proposed to drop, ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic.

CMS also finalizes the removal of one additional existing measure, ACO #26, Diabetes Mellitus: Daily Aspirin or Antiplatelet Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease. As noted above, CMS is also finalizing the removal of this measure from PQRS.

CMS also finalizes the proposal to modify the name and specifications for existing ACO measure #11, which will 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 will continue to be doubly weighted.

CMS notes that the CAD Composite will be removed since there is only one CAD measure remaining.

Table 81 of the final rule lists all 33 measures that will 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 will be assessed. CMS says that all 37 measures will be phased in for ACOs with 2015 start dates per the pay for performance phase in information provided in Table 81. Table 82 of the final rule (reproduced below) provides the number of measures by domain and total points and domain weights for scoring purposes, as a result of the final rule.

Table 82: Number of Measures and Total Points for Each Domain within the Quality Performance Standard

<table>
<thead>
<tr>
<th>Domain</th>
<th>Number of Individual Measures</th>
<th>Total Measures for Scoring Purposes</th>
<th>Total Possible Points</th>
<th>Domain Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient/Caregiver Experience</td>
<td>8</td>
<td>8 individual survey module measures</td>
<td>16</td>
<td>25%</td>
</tr>
<tr>
<td>Care Coordination/ Patient Safety</td>
<td>10</td>
<td>10 measures. Note that the EHR measure is double-weighted (4 points)</td>
<td>22</td>
<td>25%</td>
</tr>
<tr>
<td>Preventive Health</td>
<td>8</td>
<td>8 measures</td>
<td>16</td>
<td>25%</td>
</tr>
<tr>
<td>At-Risk Population</td>
<td>7</td>
<td>5 individual measures, plus a 2-component diabetes composite measure, scored as one</td>
<td>12</td>
<td>25%</td>
</tr>
<tr>
<td>Total in all Domains</td>
<td>33</td>
<td>32</td>
<td>66</td>
<td>100%</td>
</tr>
</tbody>
</table>
In the proposed rule, CMS noted 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. However, CMS is convinced by commenters that an additional year of pay for reporting is needed by CMS and ACOs to fully implement new measures. Thus, each new measure will be pay-for-reporting for its first two reporting periods of use. The phase-in schedule indicated in Table 81 of the final rule applies to a measure after it has been pay-for-reporting for the first two reporting periods it is in use.

CMS also finalizes the proposal to reduce the sample for each ACO measure reported through the CMS web interface, from 411 to 248, as it is doing under the PQRS GPRO (discussed in section III.K above). CMS notes that a few commenters were concerned that the reduced sample size may not adequately or accurately represent the diversity of an ACO’s providers and suppliers, especially for larger ACOs. These commenters supported reducing the sample size only for smaller ACOs, such as ACOs with 5,000 to 10,000 assigned beneficiaries. Alternatively, these commenters requested that ACOs be given the option to continue to report a larger sample size if they prefer. In response, CMS says it does not have a mechanism that would allow it to deviate from the established methodology used by the GPRO web interface, and therefore cannot offer an option at this time for ACOs to choose to be assessed on more than 248 patients. CMS also disagrees that the reduced sample size will not adequately represent the diversity of an ACO’s providers and suppliers because it has concluded that a sample of 248 is statistically valid and reliable.

2. Request for Comments for Future Quality Measures

In the proposed rule, CMS requested public comment on additional measures that the agency may consider in future rulemaking, and asked for input on a number of specific issues. In the final rule, CMS notes, among other things, that some commenters opposed utilization measures, believing these types of measures are not necessary within the Shared Savings Program because of the inherent incentive for ACOs to reduce unnecessary services and achieve savings. CMS also expresses appreciation for the many thoughtful suggestions it received and says it will consider them as it develops any future proposals for additional measures for the Shared Savings Program.

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 will 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 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 has 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 finalizes the proposed amendment to 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.

4. Quality Performance Benchmarks

CMS finalizes proposed 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 will 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 also finalizes the proposal to update benchmarks every 2 years. However, in response to comments, CMS agrees to use up to 3 years of FFS data to set benchmarks, if available. CMS notes, however, that the use of multiple years of data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years (and which are based on data from the 2012 reporting period). CMS also says that for newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark will be established in that year and updated along with the other measures at the start of the next 2-year benchmarking cycle. Table 84 of the final rule (reproduced below) gives the timeline for setting and updating quality performance benchmarks under the Medicare Shared Savings Program.

<table>
<thead>
<tr>
<th>Reporting period for data used to set benchmark</th>
<th>Year data is analyzed, and benchmark is published</th>
<th>Performance year and reporting period to which benchmark applies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>2013</td>
<td>2014 &amp; 2015</td>
</tr>
</tbody>
</table>

5. Rewarding Quality Improvement

In the proposed rule, CMS proposed to add a quality improvement measure to award bonus points for quality improvement to each of the existing four quality measure domains, under which 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 proposed 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, the t-test. CMS finalizes its proposal but in response to the many commenters who felt the agency had not gone far enough, it agrees to award an ACO up to four additional bonus points for quality performance improvement on the quality measures within a domain (all other aspects of the proposal remain unchanged).

6. Technical Corrections

CMS finalizes the proposed elimination of a reference to a non-existent paragraph (c) of §425.216 and the substitution of a reference to §425.216 generally, the proposed correction of a typographical error in §425.502(d)(2)(ii), and the proposed 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).

The regulatory impact analysis says that since the MSSP policies being adopted in the final rule do not increase the quality reporting burden for ACOs participating in the MSSP and their ACO participants and ACO providers/suppliers, “there is no impact for these policies.”

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.

1. Provisions of this Final Rule for the VM

As discussed below in greater detail, CMS finalizes the following provisions for the VM:

- Apply the VM to all physicians in groups with two or more eligible professionals and to solo practitioners starting in CY 2017.
- Apply the VM to all nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners starting in CY 2018.
- Make quality-tiering mandatory for groups and solo practitioners in 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 two and nine 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 and CY 2018, respectively.
- 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 for physicians in groups of 10 or more eligible professionals. For physicians in groups with 2-9 eligible professionals and solo practitioners, the amount of payment at risk under the VM will be 2.0 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 capita cost measures in the cost composite.

CMS received some general comments about the VM. These included comments that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology does not capture the additional costs associated with treating the sickest beneficiaries including beneficiaries receiving home care and SNF care. A commenter suggested excluding beneficiaries who receive a major organ transplant from cost and quality measures. Some commenters stated that groups that work exclusively in post-acute and long-term care settings are not able to perform well on cost measures under the current methodology and suggested including the place of service where beneficiaries receive care to set cost benchmarks to compare groups who treat beneficiaries in specific locations such as SNF.

CMS responds that they continue to believe their current risk adjustment methodology is appropriate and notes that the Medicare Spending per Beneficiary Measure is adjusted for costs based on whether a beneficiary recently required long-term institutional care. CMS references the FY 2012 IPPS Final Rule (76 FR 61825) for a discussion about adjusting cost measures for differences in site of service; CMS states that they believe adjustments for site of service would undermine their ability to capture differences in Medicare spending. CMS notes that they apply a specialty adjustment to all cost measures used in the VM which allows groups’ costs to be compared to similarly comprised groups, based on specialties (discussed in the CY 2013 FR, 78 FR 747776).

CMS does note that the high costs within the post-acute and long-term care settings present a “unique opportunity” for these providers to improve their performance. CMS will continue to monitor these providers’ performance under the VM and continue to explore potential risk adjustment refinements.
a. Group Size

CMS finalizes that beginning with CY 2017, the VM would be applied to physicians in groups with 2 or more eligible professionals and to solo practitioners based on the CY 2015 performance period. CMS estimates that this policy will affect approximately 900,000 physicians (See Table 86 in the final rule for more details).

- 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 is 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.
- 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 also finalizes the following policy:

- Beginning in CY 2017, under the quality-tiering methodology, a group or solo practitioner will receive a cost composite score that is classified as “average” if the group or solo practitioner does not have at least one cost measure with at least 20 cases.

Several commenters supported CMS’ proposal to expand the VM to include all physicians in solo practice and in groups with 2 or more eligible professionals. Other commenters opposed this proposal, notwithstanding the Secretary’s statutory obligation, and commented that CMS should delay the application to all physicians either through selective implementation or request Congress amend the statute. CMS disagrees citing the statutory requirement and stating that applying the VM to all physicians is essential to their ongoing efforts to improve both the quality and efficiency of care provided to beneficiaries. In response to concerns that CMS should ensure that the quality and cost measures are reliable and valid for small and solo practitioners, CMS discusses their analysis that demonstrates that the quality and cost measures are reliable for all physicians.

In response to some commenters’ concerns about the VM impact on providers who treat high-cost patients and on certain specialties with few quality measures, CMS states that PQRS may not provide specialists and subspecialists the flexibility to report on measures that are relevant to their unique patient panels but notes that physicians have flexibility in choosing their quality reporting measures and sub-specialists can participate in PQRS as members of a group practice. CMS also notes that PQRS has a
Measure Applicability Validation (MAV) process that determines PQRS incentive eligibility or potential applicability of the payment adjustment for eligible professionals and groups reporting less than the required PQRS measures (See Section III.K of this summary for discussion of the MAV and criteria for satisfactory reporting for the 2017 PQRS payment adjustment).

In response to commenters’ concerns about the short period of time that solo practitioners and groups with less than 25 eligible professionals will have to analyze their QRUR reports before the CY 2015 performance period, CMS notes that they made QRUR reports available on September 30, 2014 to all physicians based on their CY 2013 performance and they believe this is sufficient time to understand the VM and PQRS. CMS also states that their final policy to hold harmless groups with two to nine eligible professionals and solo practitioners from any downward adjustment would “likely mitigate unintended consequences that could occur” (See Section c below).

Several commenters were concerned that physicians have little experience with the PQRS program and do not understand the VM. In response, CMS urges physicians to educate themselves about PQRS and VM by using the related CMS websites: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html and http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html. CMS also will continue to work with medical and specialty societies about education programs and the QIOs will also be conducting outreach programs.

b. Application of the VM to Nonphysician EPs

CMS finalizes that beginning with CY 2018 the following policies apply:

- The VM would be applied to items and services billed under the PFS by all of the physician and nonphysician eligible professionals who bill under a group’s TIN. During the payment adjustment period, all of the nonphysician eligible professionals who bill under a group’s TIN will be subject to the same VM that will apply to the physicians who bill under the TIN.
- The VM would apply to groups that consist of only nonphysician eligible professionals who bill under a group’s TIN.
- The VM would apply to nonphysician eligible professionals in solo practice.
- 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.”
CMS also finalizes the following policy:

- In CY 2018, under the quality-tiering methodology, a group that consists only of nonphysician eligible professionals and solo practitioners who are nonphysician eligible practitioners will be held harmless from downward adjustments.

Although several commenters supported the proposal to apply the VM to nonphysician eligible professionals beginning in CY 2017, most of the commenters urged CMS to delay implementation and adopt a phased approach that provides nonphysician eligible professionals more time to understand and prepare for the VM. CMS agrees with the commenters and finalizes that the VM will apply beginning in the CY 2018 payment adjustment period. CMS notes that they will propose a performance period for the CY 2018 payment adjustment period in the CY 2016 PFS proposed rule and that in prior rulemaking for the VM they finalized the performance period as two calendar years prior to the beginning of the payment adjustment year. (Based on prior rulemaking, CY 2016 should be the performance year for the CY 2018 payment adjustment period for the VM.)

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

CMS finalizes the application of the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017 except that solo practitioners and groups with two to nine eligible professionals in Category 1 would be held harmless from any downward adjustments in the quality-tiering methodology for the CY 2017 VM.

For purposes of the CY 2017 VM, CMS finalizes the two-category approach based on participation in the PQRS by groups and solo practitioners:

**Category 1 would include:**

- Groups that meet the criteria for satisfactory reporting of 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 would include groups and solo practitioners that are subject to the CY 2017 VM and do not meet the criteria for Category 1.

Most commenters supported CMS’ proposal to hold harmless groups with two to nine eligible professionals and solo practitioners from downward payment adjustments in CY 2017. Many commenters were concerned about CMS’ proposal to apply a downward adjustment to groups with 10 or more eligible professionals because the maximum downward adjustment would be -4.0 percent; commenters made several recommendations for phasing in the downward adjustment. CMS believes that groups with 10 or more eligible professionals have sufficient information with the quality measures in the VM and that QRUR reports were made available in September to all physicians. CMS is also considering providing semi-annual QRURs with updated cost and resource use information to groups and solo practitioners. In response to concerns about the financial impact of applying quality-tiering to small groups and solo practitioners in CY 2017, as discussed below in section f, CMS finalizes a policy to apply a -2.0 percent VM to groups with two to nine professional and solo practitioners that are in Category 2 in CY 2017.

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 are CMS’ final policies for applying the VM 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

a. Application of the VM

Beginning with the CY 2017 payment adjustment period, CMS finalizes the policy to apply the VM to physicians in groups with two or more eligible professionals and to physicians 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 finalizes, that beginning with the CY 2018 payment adjustment, the VM will apply to nonphysician eligible professionals in groups with two or more eligible professionals and to 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).

Many commenters suggested that CMS should continue to exempt Shared Savings Program participants from the VM. CMS disagrees citing statutory requirements and
their belief that alignment of quality reporting and quality measurements is important for improvement of care provided to beneficiaries.

b. Calculation of the cost composite of the VM
CMS finalizes the cost composite as “average cost” for groups and solo practitioners that participate in an ACO under the Shared Savings Program.

- CMS finalizes that if a group or solo practitioner participates in an ACO during the applicable performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period), then the group or solo practitioner’s cost composite will be classified as “average cost”, regardless of whether the group or solo practitioner participates in an ACO during the payment adjustment period.
- CMS finalizes that the VM calculated under this policy will apply to all physicians billing under the group’s TIN in the CY 2017 payment period, regardless of whether the professional was part of the group in the performance period.

Many commenters were concerned about applying the VM to ACO participants but stated that if CMS were to apply the VM to ACO participants, CMS should classify the cost composite as “average cost” because of the different methodologies for assessing cost performance in the two programs. A few commenters stated that participants in an ACO should have their cost composite calculated without regard to participation in an ACO because CMS’ policy would limit a potential upward adjustment under the VM to participants in an ACO. In response, CMS notes that they will explore how to calculate a VM cost composite at the ACO level and would address this issue in future rulemaking. CMS states that they were convinced by comments objecting to their proposal to take into account a group or solo practitioner’s participation in an ACO during the payment adjustment period for the VM and changed this policy to respond to commenters.

c. Calculation of the quality composite under the VM
CMS finalizes calculation of the quality of care composite score based on the quality-tiering methodology using quality data submitted by the ACO from the performance period and applying the same quality composite to all groups and solo practitioners, as identified by TIN, under that ACO.

- CMS finalizes that if a group or solo practitioner participates in an ACO during the applicable performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period), then the group or solo practitioner’s quality composite will be calculated using the ACO-level quality data from the performance period, regardless of whether the group or solo practitioner participates in an ACO during the payment adjustment period or moves to another ACO.
- CMS finalizes that the VM calculated under this policy will apply to all physicians billing under the group’s TIN in the CY 2017 payment period, regardless of whether the professional was part of the group in the performance period.
- Consistent with the application of the VM to other groups and solo practitioners that report under PQRS, if an ACO does not successfully report quality data as required by the Shared Savings Program, all groups and solo practitioners...
participating in the ACO will fall in the Category 2 for the VM and be subject to the downward payment adjustment.

- CMS finalizes they will use the all cause hospital readmissions measure calculated for ACOs for inclusion in the quality composite for the VM for groups and solo practitioners.

As noted above in the discussion of the cost composite, CMS received many comments stating that groups and solo practitioners participating in an ACO should be exempt from the VM. Many commenters were concerned about the potential for conflicting incentives when applying the VM to Shared Savings Program participants and suggested an “Innovation Pathway” approach for participants in the Shared Savings Program and Innovation Center initiatives in which ACO participants would receive “average cost” and “average quality” unless they opted to have a VM calculated. CMS disagrees and states they believe it is appropriate to calculate a quality composite for ACO participants. CMS also does not believe that the differences between quality methodologies for the VM and the ACO creates significant confusion or conflicting results. CMS notes that the GPRO web interface quality measures used in the Shared Savings Program are the same as those used to calculate the quality composite of the VM for groups that are not in an ACO and report through GPRO. In addition, CMS notes that since ACOs report on quality measures on behalf of all the groups and solo practitioners that participate in the ACO, they can calculate a single quality composite that can apply to all participants. As with the cost composite, CMS states that they were convinced by comments objecting to their proposal to take into account a group or solo practitioner’s participation in an ACO during the payment adjustment period for the VM and changed this policy to respond to commenters.

d. Treatment of groups with two to nine eligible professionals and solo practitioners
Consistent with the policy finalized to hold harmless from any downward adjustments groups with two or nine eligible professionals and solo practitioners for the CY 2017 VM, CMS extends this hold harmless policy to groups with two or nine eligible professionals and solo practitioners who participate in an ACO for the CY 2017 VM.

CMS also notes that they will follow their established process for determining group size as described at §414.1210(c). Therefore, to the extent that a quality of care composite can be calculated for an ACO and the cost composite would be classified as “average cost”, groups with 10 or more eligible professionals participating in an ACO would be subject to an upward, neutral, or downward payment adjustment in CY 2017. CMS will also apply an additional upward payment of +1.0x for caring for high risk beneficiaries (see summary discussion in section f).
2. **Physicians and Nonphysician Eligible Professionals that Participate in the Pioneer ACO Model, the Comprehensive Primary Care (CPC) Initiative, or Other Similar Innovation Models or CMS Initiatives**

   a. **Application of the VM to participants in the Pioneer ACO Model and CPC Initiative**

   Beginning with the CY 2017 payment adjustment period, CMS finalizes the policy to apply the VM to physicians in groups with two or more eligible professionals in which at least one eligible professional participates in the Pioneer ACO or CPC Initiative, and to physicians who are solo practitioners that participate in the Pioneer ACO or the CPC Initiative.

   The majority of commenters were opposed to applying the VM to the Pioneer ACO and CPC Initiative, similar to the comments about applying the VM to ACO participants. A few commenters suggested that the application of the VM to Innovation Center initiatives should be waived under section 1115A of the Act. A commenter suggested the VM should be waived until these programs end on December 31, 2016. In response, CMS reiterates they are statutorily required to apply the VM to all physicians beginning January 1, 2017.

   b. **Calculation of the cost and quality composite of the VM for Pioneer ACO and CPC Initiative participants**

   CMS finalizes the following policies:
   
   - For solo practitioners and groups with at least one eligible professional participating in the Pioneer ACO or CPC Initiative during the performance period, CMS will classify the cost composite as “average cost” and the quality composite as “average quality” for the CY 2017 payment adjustment period.
   - The VM will apply to all physicians billing under the group’s TIN in the CY 2017 payment adjustment period regardless of whether the physician was part of the group in the performance period.
   - For groups or solo practitioners who participate in a Pioneer ACO or CPC Initiative in the performance period and then participate in an ACO in the payment adjustment period, these providers will also receive “average cost” and average quality”.

   CMS supports comments that costs and quality composites should be classified as average and incorporates this into their final policy as noted above. CMS notes that similar to an ACO, these models use a shared savings methodology that is significantly different than the cost measures and benchmarks used to calculate the cost composite under the VM. It is also challenging to meaningfully assess the quality performance of groups participating in these models because the quality data does not necessarily represent the eligible professionals in the group since some of the group’s physicians do not participate in the model. As with the ACO proposal, CMS states that they were convinced by comments objecting to their proposal to take into account a group or solo practitioner’s participation in the Pioneer ACO or CPC Initiative during the payment adjustment period for the VM and changed this policy to respond to commenters.
c. Application of the VM to Other CMMI Models or CMS Initiatives

Beginning with the CY 2017 payment adjustment period, CMS finalizes applying the same VM to physicians in groups with two or more eligible professionals and to physician who are solo practitioners that participate in other similar CMMI models or CMS initiatives during the relevant performance period for the VM, in accordance with the proposed policies described above for the Pioneer ACO Model and the CPC Initiative.

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

- The model or initiative evaluates the quality of care and/or requires reporting on quality measures;
- The model or initiative evaluates the cost of care and/or requires 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 these criteria are intended to serve as a general framework for evaluating models and initiatives. If CMS determines that a model or initiative falls under the “other similar” category, CMS finalizes they will 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 finalizes their clarification that starting in CY 2015, they will apply the VM only to assigned services 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.

CMS received a comment that a similar policy should be applied to the PQRS and EHR meaningful use adjustments. CMS notes that this comment is outside of the scope of the proposed rule. They note however, that the VMS is quite different from the PQRS and EHR meaningful use adjustments, which apply to the Medicare allowed amount rather the Medicare paid amount.

f. Payment Adjustment Amount

Section 1848(p)(4)(C) of the Act requires the VM to be implemented in a budget neutral manner.
For CY 2017, CMS finalizes the following policies:

- Apply a -4.0 percent VM to groups with ten or more eligible professionals that fall in Category 2. Apply a -2.0 percent VM to groups with two to nine eligible professionals or 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 with ten or more eligible professionals classified as low quality/high cost. Groups with between 2 and 9 eligible professional and solo practitioners in Category 1 will be held harmless from any downward adjustments in CY 2017.
- Increase the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0x for groups with ten or more eligible professionals classified as high quality/low cost and to set the adjustment to +2.0x for groups and solo practitioners as high quality/low costs.
- Provide an additional upward payment adjustment of +1.0x to groups and solo practitioners that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population).

Tables 88 and 89, reproduced below, show the final CY 2017 quality-tiering payment adjustment amounts.

**TABLE 88: Final CY 2017 VM Payment Adjustment Amounts for Groups with Two to Nine Eligible Professionals and Solo Practitioners**

<table>
<thead>
<tr>
<th>Cost/Quality</th>
<th>Low Quality</th>
<th>Average Quality</th>
<th>High Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Cost</td>
<td>+0.0%</td>
<td>+1.0x*</td>
<td>+2.0x*</td>
</tr>
<tr>
<td>Average Cost</td>
<td>+0.0%</td>
<td>+0.0%</td>
<td>+1.0x*</td>
</tr>
<tr>
<td>High Cost</td>
<td>+0.0%</td>
<td>+0.0%</td>
<td>+0.0%</td>
</tr>
</tbody>
</table>

*Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.

**TABLE 89: Final CY 2017 VM Payment Adjustment Amounts for Groups with Ten or More Eligible Professionals**

<table>
<thead>
<tr>
<th>Cost/Quality</th>
<th>Low Quality</th>
<th>Average Quality</th>
<th>High Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Cost</td>
<td>+0.0%</td>
<td>+2.0x*</td>
<td>+4.0x*</td>
</tr>
<tr>
<td>Average Cost</td>
<td>-2.0%</td>
<td>+0.0%</td>
<td>+2.0x*</td>
</tr>
<tr>
<td>High Cost</td>
<td>-4.0%</td>
<td>-2.0%</td>
<td>+0.0%</td>
</tr>
</tbody>
</table>

*Groups eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.
The majority of commenters were opposed to CMS' proposals to increase the maximum downward payment adjustments from CY 2016 to CY 2017 for groups and solo practitioners to -4.0 percent. CMS agrees with these concerns and with the commenters who suggested that smaller groups should be subject to a more gradual phase-in of the VM, consistent with the policy for larger groups; the final policy reflects these concerns.

CMS also finalizes that they may update the payment adjustment factors, depending on the outcome of the informal inquiry process (see discussion below, section 4i).

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 finalizes including 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.

PQRS Quality Measures: For the VM in CY 2017, CMS finalizes using all of the quality measures that are available to be reported under the various PQRS 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 submits data on these measures. CMS also finalizes the following policies:

- Groups with 2 or more eligible professionals can elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015
- Continue to include the three outcome measures in the quality measures: (1) composite 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) rate of an all-cause hospital readmissions measure.
  - CMS also finalizes their clarification that they calculate benchmarks for these 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).
- For groups that are assessed under the “50 percent option”, CMS will calculate the group’s performance rate for each measure reported by at least one eligible professional in the group by combining the weighted average of the performance rates of those eligible professional reporting the measure.
For groups that are assessed under the “50 percent option”, CMS will 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 qualified clinical data registry, CMS will 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 the performance on that measure will not be included in the quality composite. CMS finalizes applying this policy to new measures reported through a PQRS qualified clinical data registry (defined as measures that were not previously reported in PQRS). CMS notes that once they have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure’s performance rate during the year prior to the performance period.

In response to comments about the lack of applicable quality measures for multiple specialties, CMS reiterates their belief that group reporting can help reduce these concerns and that eligible professionals and groups concerned about the lack of specialty measures to meet PQRS reporting requirements should review the PQRS MAV process. In response to comments suggesting that CMS expand the data collected on the CAHPS measures, CMS states they will consider these suggestions in future refinements. CMS also notes that any expansion of mandatory CAHPS inclusion in the VM would occur through future notice and comment rulemaking.

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 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 practitioners participating in an ACO, CMS finalizes using the quality measures that are identical to the two programs.

- For the CY 2017 payment adjustment period, CMS finalizes using 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.
- CMS finalizes using the all-cause hospital readmission measure calculated for ACOs in the VM for the CY 2017 payment adjustment period.
- CMS finalizes not to include outcome measures that are not currently calculated for ACOs: (1) a composite of rates of potentially preventable hospital admissions for HF, COPD, and diabetes; and (2) a composite of rates of potentially preventable hospital admissions for dehydration, UTIs, and bacterial pneumonia.

To determine the standardized scores for these quality measures, CMS finalizes applying the VM benchmarks, which are the national mean for a measure’s
performance based on data from one year prior to the performance period to determine the standardized score for quality measures for groups and solo practitioners participating in ACOs.

CMS disagrees with commenters’ concerns that utilizing the GPRO Web Interface measures will cause additional reporting burden because the ACO GPRO Web-Interface measures and PQRS GPRO Web-Interface measures are the same. In response to commenters’ concerns that their performance will be poor in comparison to providers not participating in ACOs because the ACO providers will be measured against the VM national benchmarks, CMS replies that although the benchmarking methodology is different (the VM uses a national weighted mean and the ACO uses a decile distribution for measuring performance), they believe using the same data source enables a fair comparison. CMS also notes they believe it is appropriate to use the ACOs’ all-cause readmission measure for calculating the VM because they believe it is equivalent to the all-cause hospital readmission measure used for the VM.

All-Cause Hospital Readmission Measure: Beginning with the CY 2017 payment adjustment period, CMS finalizes changing 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 finalizes excluding 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.

One commenter stated that the all-cause readmission measure was still not appropriate for physician accountability because the readmission costs are already included in the total per capita costs, the measure was not specified for group level measurement, and the measure was not supported by the Measure Applications Partnership (MAP). CMS disagrees and notes that the all-cause hospital readmission measure is a measure of readmission rates, not of costs and that the MAP did support the measure’s “direction”.

In response to concerns about the reliability of this measure, CMS notes that their analysis of 2012 data 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 and scores greater than 0.7 are considered high.

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 2013 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.

CMS is finalizing the following policies:

- For the CY 2015 payment adjustment period:
  - February 28, 2015 as the deadline for a group to request correction of a perceived error made by CMS in the determination of the CY 2015 VM payment adjustment.
  - Classify a TIN as “average” quality if CMS determines that they made an error in the calculation of the quality composite.
  - Recompute a TIN’s cost composite if CMS determines they made an error.
  - Adjust a TIN’s quality-tier if CMS makes corrections to a TIN’s quality and/or cost composites as a result of this correction process.

- Beginning with the CY 2016 payment adjustment period:
  - A 60-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.
  - CMS will take steps to establish a process for accepting requests from providers to correct certain errors made by CMS or a third-party vendor. CMS notes they also intend to use this process to recompute a TIN’s quality and/or cost composite when they determine an erroneous calculation. CMS notes that if the operational infrastructure is not available to allow this recomputation, CMS will continue to use the FY 2015 approach.

For both the CY 2015 payment adjustment period and future adjustment periods, CMS will adjust a TIN’s quality-tier if CMS makes a correction to a TIN’s quality and/or cost composite as a result of the correction process. CMS will provide additional operational details in sub-regulatory guidance.

CMS notes there would be no administrative or judicial review of the determination resulting from this expanded informal inquiry process.

Commenters supported implementing an expanded informal inquiry process to allow for corrections to the VM. Almost all commenters requested a later deadline for submission of VM corrections and CMS extended the deadlines in the finalized policy. In response to comments objecting to the proposal for 2015 to classify a TIN as “average quality”, CMS states that it will not be operationally feasible for them to fully evaluate errors with regard to quality measures for the CY 2015 payment adjustment period but they are working to have an operational infrastructure 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 finalizes policies to address two of the NQF’s concerns: (1) modifications to the two-step attribution methodology and (2) reversing the current exclusion of certain Medicare beneficiaries during the performance period. These changes begin with the CY 2017 payment adjustment period for the VM and would apply to all five of the total per capita cost measures.

Attribution Methodology
Beginning with the CY 2017 payment adjustment period, CMS finalizes the following changes for the VM that will apply to all five of the total per capita cost measures:

- Step 1 of the attribution rule will 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 practitioners 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.

Many commenters opposed including NPs, PAs and CNSs in the first step of the attribution methodology because these nonphysician practitioners are not necessarily practicing in a primary care setting and there is no specialty distinction on claims billed by these practitioners. CMS appreciates these concerns and notes that an analysis of 2011 data for groups of 25 or more eligible professionals found over 97 percent of beneficiaries were attributed to the same group that they had been attributed to under the current methodology. CMS notes they will continue additional analysis and will monitor the effect of these changes to ensure they are not having a disproportionately negative effect on a subset of provider types.

Exclusion of Certain Beneficiaries
Beginning with the CY 2017 payment adjustment period, CMS finalizes including certain part-year beneficiaries in the five total per capita cost measures used in the VM:

- Medicare FFS beneficiaries who are at the end of life in the performance period; and
- Medicare FFS beneficiaries who are newly enrolled in Medicare during the performance period and are enrolled in both Part A and Part B.
CMS will continue to exclude other part-year beneficiaries:
- Medicare FFS beneficiaries who spend part of the performance period in a Part C (Medicare Advantage) plan; and
- Medicare FFS beneficiaries 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.

Some commenters opposed the proposal because they believe the inclusion of beneficiaries at the end of life will include typically higher cost beneficiaries and would inappropriately disadvantage groups that treat a large percentage of beneficiaries at the end of life. One commenter suggested that CMS should develop an end of life specific cost and quality measure. CMS states that analysis which they will be posting to the VM website shows moderate reliability for the five per capita cost measures with the inclusion of certain part-year beneficiaries. CMS also notes that they believe the inclusion of newly eligible beneficiaries, who are typically much lower cost, may offset some of the increased costs associated with beneficiaries at the end of life. CMS will take into consideration the development of specific measures for the end of life.

CMS notes they are not addressing other concerns about the total per capita cost measures raised by NQF, including the issue of socioeconomic status and the risk adjustment methodologies, and including Part D data in these measures. Many comments emphasized the importance of including socioeconomic status in measures and CMS states they will take into account the August 2014 NQF report and the NQF recommendations as they consider potential future refinements to the risk adjustment methodologies. Many commenters also supported including Part D expenditures in cost measures; CMS responds they are investigating options for including Part D expenditures. CMS notes that they would propose any options under future notice and comment rulemaking.

**k. Discussion Regarding Treatment of Hospital-Based Physicians**

CMS requested comments about a policy that would include or allow groups that include hospital-based physicians or solo practitioners to elect the inclusion of the Hospital Value-Based Purchasing (VBP) Program performance in their VM calculation.

CMS appreciates the comments they received and will take these into consideration as they continue to refine the VM and improve the coordination between the HVBP and VM. CMS notes any change would be proposed through future notice and comment rulemaking.

**l. Regulatory Impact Analysis**

CMS notes that the finalized changes in the VM discussed in this final rule would not impact the CY 2015 physician payments under the PFS.
CMS summarizes their 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. Based on the methodology codified in §414.1210(c) there are 1,010 groups with 100 or more eligible professionals (as identified by their TINs) whose physicians’ payments under the PFS will be subject to the VM in the CY 2015 payment adjustment period. Of these 1,010 groups, 706 met the criteria for inclusion in Category 1. Of the 706 groups in Category 1, 133 groups elected in 2013 to have their CY 2015 VM calculated using the quality-tiering method. Twenty-one groups that elected to have quality-tiering had insufficient data for calculating their quality or cost composite and they will receive a neutral adjustment to their payments in CY 2015. Of the remaining 112 groups, 16 groups will have an upward adjustment of +1.0x (no group was eligible to receive an additional +1.0x adjustment for treating high-risk beneficiaries); 9 groups will have a downward adjustment of between 0.5 and -1.0 percent; and 87 groups will have a neutral adjustment to their payment in CY 2015. Table 98 reproduced below shows the distribution of the 112 groups that had quality-tiering.

TABLE 98: Distribution Using 2013 Data of Quality and Cost Tiers for Groups with 100 or More Eligible Professionals that Elected Quality-Tiering for Which a Quality or Cost Composite Score Could Be Calculated (112 Groups)

<table>
<thead>
<tr>
<th>Cost/Quality</th>
<th>Low Quality</th>
<th>Average Quality</th>
<th>High Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Cost</td>
<td>+0.0%</td>
<td>+1.0x</td>
<td>+2.0x</td>
</tr>
<tr>
<td></td>
<td>(0)</td>
<td>(2)</td>
<td>(0)</td>
</tr>
<tr>
<td>Average Cost</td>
<td>-0.5%</td>
<td>+0.0%</td>
<td>+1.0x</td>
</tr>
<tr>
<td></td>
<td>(5)</td>
<td>(87)</td>
<td>(14)</td>
</tr>
<tr>
<td>High Cost</td>
<td>-1.0%</td>
<td>-0.5%</td>
<td>+0.0%</td>
</tr>
<tr>
<td></td>
<td>(2)</td>
<td>(2)</td>
<td>(0)</td>
</tr>
</tbody>
</table>

Of the 706 groups in Category 1, 573 groups elected to not have their CY 2015 VM calculated using the quality-tiering methodology and their VM will be 0.0 percent.

Of the 1,010 groups subject to the CY 2015 VM, 304 groups met the criteria for inclusion in Category 2; 289 groups did not self-nominate for the PQRS and 15 groups that self-nominated for the PQRS did not report at least one measure. These groups in Category 2 will be subject to a -1.0 percent payment adjustment.

CMS will announce the upward payment adjustment factor (x) in the Fall of 2014 on their website at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html).
2. Physician Feedback Program

In September 2014, CMS made available QRURs based on CY 2013 data to all physicians. CMS notes these reports 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.

CMS will continue 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 heart 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.

b. Future Plans for Physician Feedback Reports

CMS notes they will continue to develop and refine the annual QRURs in an iterative manner and welcomes suggestion from stakeholders.

Commenters supported the Physician Feedback Program and CMS’ continued efforts to improve the QRURs. Many providers wanted them earlier in the year and CMS noted that although that is not feasible they are exploring how to provide semi-annual reports. Several commenters suggested that QRURs should be distributed to all providers, including nonphysician eligible professionals; CMS does not respond to this comment.

O. Establishment of the Federally Qualified Health Center Prospective Payment System (FQHC PPS)

In May 2014, CMS published the “FQHC PPS final rule” (79 FR 25436). This final rule with comment period implemented payment rates for FQHC services under Medicare Part B beginning on October 1, 2014. In the FQHC PPS final rule with comment period, CMS invited comments on the issues summarized in this section. CMS notes that they received many comments that were beyond the scope of specific proposals related to the FQHC PPS.
1. Promoting integrated and coordinated care in FQHCs and RHCs through payment for Chronic Care Management Services

In the FQHC PPS final rule, CMS invited comments on how payment for CCM services could be adapted for FQHCs and RHCs to help promote integrated and coordinated care.

CMS received a few comments supporting the adoption of the CCM provisions in FQHCs but many commenters had concerns about the unique challenges FQHCs would have implementing CCM. Commenters stated that the CCM requirements for electronic exchange of health records would be difficult since many FQHCs are still working on developing interoperability with other providers. Another challenge cited was the requirement to provide patients with secure messages via the internet since many FQHC patients do not have internet or email. Commenters also urged that any implementation requirements would not place an undue burden on health centers or the patients. CMS notes they will take comments into consideration.

2. Exceptions to the per diem FQHC PPS payment for subsequent illness or injury and mental health services furnished on the same day as a medical visit

Under the FQHC PPS, Medicare pays a FQHC for more than 1 visit per day for 2 reasons: (1) the patient suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day or (2) has a medical health visit and a mental health visit on the same day.

CMS received many comments on this policy that were all supportive of the policy. Most commenters, however, requested additional exceptions to the per diem PPS payment policy. Many commenters noted that under the all-inclusive rate (AIR) system, DSMT/MNT services and the IPPE can be billed separately when furnished on the same day as another billable visit and requested these services have an exception under the PPS. In response, CMS states that to accurately pay FQHCs for the cost of furnishing an IPPE, they added an adjustment factor of 1.33 to the PPS when an IPPE is furnished at a FQHC. CMS notes that their analysis of claims and cost reporting data does not justify a separate per diem payment or an adjustment to the PPS rate. CMS also states that DSMT/MNT services are part of the broad category of primary care services that are included in the services of a FQHC and are part of the PPS per diem payment. CMS retains their current policy for exceptions to the per diem FQHC PPS payment.

3. Establishment of FQHC G-codes to report and bill FQHC visits to Medicare under the PPS

In the FQHC PPS final rule, CMS stated that establishing HCPCS G-codes for FQHCs to report and bill for Medicare visits would allow comparison between the PPS per diem rate and a FQHC’s charge for a per diem visit. CMS established a new set of HCPCS
G-codes for FQHCs to report an established Medicare patient visit, a new or initial patient visit, and an IPPE or AWV.

CMS received several comments on the establishment of G codes. Most commenters favored using G-codes but commenters expressed concerns about the complexity and administrative burden of implementing these codes. CMS acknowledges that FQHCs are unfamiliar with G-codes for payment under the PPS and provides a list of resources including slides from a training presentation that is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html. CMS also acknowledges that transitioning to a new payment system will require time as all aspects of the billing system will need to be adapted, including the need to spend additional time explaining changes in charges and a patient’s EOB. After reviewing comments, CMS retains the FQHC G-codes as defined in program instructions.

4. Waiving coinsurance for preventive services when furnished with other services under the FQHC PPS

In the FQHC PPS final rule, CMS decided to retain the current method used under the AIR system for calculating coinsurance when there is a mix of preventive and non-preventive services, with certain modifications. Under the FQHC PPS, the dollar value of the FQHC’s reported line-item charge for the preventive service will be subtracted from the full payment amount, whether payment is based on the FQHC’s charge or the PPS rate. Medicare will pay the FQHC 100 percent of the dollar value of the FQHC’s reported line-item charge for the preventive service. Medicare will pay a FQHC 80 percent of the remainder of the full payment and the beneficiary coinsurance would be 20 percent of the remainder of the full payment.

CMS received many comments on how this policy was too complex and burdensome to implement. Some commenters stated that it would be more consistent with the regulation if CMS completely waived coinsurance for visits involving a mixture of preventive and non-preventive services instead of implementing a partial coinsurance methodology. CMS states that they believe that the methodology is responsive to concerns and provides as much simplicity as possible while enabling FQHCs to comply with the statutory requirements for the collection of coinsurance. CMS finalizes the current approach to waiving coinsurance for preventive services.

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

CMS specifies that the entire scope of designated health services (DHS) for purposes of the physician self-referral prohibition is defined in a list of CPT/HCPCS codes (the Code List) which is updated annually to account for both changes in the most recent CPT and HCPCS publications and changes in Medicare coverage policy and payment status. The updated comprehensive Code List effective January 1, 2015 is available on the
Tables 90 and 91 of the rule identify additions and deletions to the list. Additions and deletions involve clinical laboratory services; physical therapy, occupational therapy and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; and preventive screening tests, immunizations, and vaccines. **CMS will consider comments regarding these changes.**

Q. Interim Final Revisions to the Electronic Health Record (EHR) Incentive Program

In September 2014, CMS and ONC published the “2014 CEHRT Flexibility rule” (79 FR 52910-52933). This final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to issues related to 2014 Edition CEHRT availability delays to continue to use 2011 Edition CEHRT or a combination of 2011 Edition and 2014 Edition CEHRT for the EHR reporting periods in CY 2014 and FY 2014, respectively. The final rule also made changes to the attestation process to support these flexible options for CEHRT; the final rule did not alter the attestation or hardship exception application deadlines for 2014.

After publication of the 2014 CEHRT Flexibility rule, CMS and ONC became aware that providers were confused over their ability to use the flexible options provided under the rule, especially given the unchanged attestation deadlines. Providers were concerned that their inability to use the flexible options would subject them to a payment adjustment in 2015 under Medicare for failing to demonstrate meaningful use of CEHRT, especially because the hardship exception application for EPs (July 1, 2014) and eligible hospitals (April 1, 2014) had already passed. In addition, EPs who had never successfully attested to meaningful use for the EHR Incentive Program were especially affected because they would not be able to use the flexibility options outlined in the 2014 CEHRT Flexibility rule before the October 1, 2014 deadline to avoid the payment adjustment in CY 2015, because these options could not be made available in the CMS Registration and Attestation System in time.

To ensure that all providers can use the flexible options for an EHR reporting period in 2014, and ensure that providers are not potentially subjected to the 2015 payment adjustment under the Medicare EHR Incentive Program, CMS is recognizing a hardship exception under the established category of “extreme and uncontrollable circumstances” under 42CFR §495.102(d)(4)(iii) for EPs and §412.64(d)(4)(ii)(B) for eligible hospitals, pursuant to the Secretary’s discretionary hardship exception authority. An extreme and uncontrollable circumstance hardship exists if the following two criteria are met:

1. The provider must not have been able to fully implement the 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability; and
2. The provider must not have been able to attest by their attestation deadline in 2014. (Using the flexibility options, EPs must not have been able to attest by October 1, 2014 and eligible hospitals must not have been able to attest by July 1, 2014.)

An extreme and uncontrollable circumstance hardship exception under this interim final rule is only for the 2015 payment adjustment. CMS notes that this exception would also apply to CAHs but has little impact on CAHs because the hardship exception application deadline for CAHs for the 2015 payment adjustment is November 30, 2015. Given this application deadline, CAHs have time to attest using the flexibility options.

For purposes of the 2015 payment adjustment under the Medicare EHR Incentive Program, for providers who meet the criteria for an extreme and uncontrollable circumstance hardship, CMS is extending the hardship exception application submission deadline to November 30, 2014. CMS notes they will not extend, reopen or reconsider the hardship exception application deadline for the 2015 payment adjustment for any other reason. CMS is making regulatory amendments to allow hospitals to take advantage of the extreme and uncontrollable hardship exception and the November 30, 2014 deadline.

Because there may be future situations that would warrant extending the July 1st deadline for EPs, the April 1st deadline for eligible hospitals, and the November 30th deadline for CAHs, CMS is amending the regulation text for the other hardship exception categories to allow them to specify a later deadline for submission of hardship exception applications. CMS notes that they do not intend to exercise this flexibility to extend the hardship exception application submission deadline frequently and that providers should expect to adhere to the dates specified in the regulation text.

IV. Waiver of Proposed Rulemaking and Waiver of Delay of Effective Date

This section provides CMS' determinations to waive proposed rulemaking and instead issue a final rule with comment period with interim RVUs for certain HCPCS codes discussed elsewhere in this summary. CMS is providing a 60-day public comment period for codes with interim values.

CMS states that they find good cause to waive the notice and comment procedures for the FQHS PPS rates and adjustments. CMS considers these revisions as technical corrections to the regulations, without making any substantive changes.

CMS notes that the “60-day delay in effective date can be waived if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued”. CMS states they find good cause to waive the 60-day delay in the effective date for the Interim Final Revisions to the EHR Incentive Program. CMS is still providing a 60-day comment period for these revisions.
V. 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 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.

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 $35.8013 based upon the zero percent update and the adjustments necessary to maintain budget neutrality. CMS estimates of the impacts are based upon this CF being applicable throughout the year.

In the absence of further Congressional action, CMS notes 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 93 of the final 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).
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 is expected to result in modest payment increases for family practice, internal medicine, and geriatrics.

2. Changes in PE RVUs are generally related to the RUC recommendation regarding the film-to-digital migration of imaging input. This policy primarily affects portable x-ray suppliers, diagnostic testing facilities, and interventional radiology. Payment of CCM services has a positive impact on the PE RVUs attributable to family practice, internal medicine, and geriatrics.

3. Changes in MP RVUs are primarily attributable to the changes made 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 these 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 93 shows the estimated CY 2015 combined impact on total allowed charges by specialty of all the RVU and other changes. The combined impacts were modest across specialties ranging from an increase of 1 percent for ten specialties: emergency medicine, family practice, geriatrics, hematology/oncology, infectious disease, internal medicine, neurosurgery, nurse practitioner, physical/occupational therapy, and radiation therapy centers) to a decrease of 2 percent for four specialties: dermatology, diagnostic testing facility, ophthalmology, and portable x-ray supplier.

Table 94 (Impact of Final Rule with Comment Period on CY 2015 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the changes. CMS shows the change in both facility rates and nonfacility rates for these codes, and payments based on the CY 2015 CF of $35.8013 effective January 1 to March 31, 2015 and a CF of $28.2239 effective April 1, 2015.

B. Impacts of Other Provisions of the Final Rule

CMS believes that many of the other provisions in this final rule will 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 changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary.
C. Impact on Beneficiaries

CMS notes that many of the policy changes could result in a change in beneficiary liability as it relates to coinsurance. For example, as shown in Table 94, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $108.18 which means a beneficiary would be responsible for $21.64 (20 percent of the amount). Based on this final rule, using the January 1 through March 31, 2015 CF of $35.8013, the CY 2015 national payment amount for the same code is $109.19, which means a beneficiary coinsurance for this service of $21.84.

CMS notes that changing the definition of the colorectal cancer screening test to include anesthesia, results in beneficiary liability not being applied to anesthesia billed in conjunction with a colorectal cancer screening test.
<table>
<thead>
<tr>
<th>Specialty</th>
<th>(B) Allowed Charges (mil)</th>
<th>(C) Impact of Work RVU Changes</th>
<th>(D) Impact of PE RVU Changes</th>
<th>(E) Impact of MP RVU Changes</th>
<th>(F) Combined Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL</td>
<td>$88,045</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
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<td>(A) Specialty</td>
<td>(B) Allowed Charges (mil)</td>
<td>(C) Impact of Work RVU Changes</td>
<td>(D) Impact of PE RVU Changes</td>
<td>(E) Impact of MP RVU Changes</td>
<td>(F) Combined Impact</td>
</tr>
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<td>Specialty</td>
<td>(A) Allowed Charges (mil)</td>
<td>(B) Impact of Work RVU Changes</td>
<td>(C) Impact of PE RVU Changes</td>
<td>(D) Impact of MP RVU Changes</td>
<td>(E) Combined Impact</td>
</tr>
<tr>
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</table>

**Notes:** Table 93 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the April 2015 conversion factor change required 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 93:

- **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 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 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 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.