Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016
[CMS-1631-P]

Summary of Proposed Rule

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I. Introduction and Background

On July 8, 2015, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2016\(^1\) and other revisions to Medicare Part B policies. The proposed rule is slated for publication in the July 15, 2015 issue of the Federal Register. If finalized, policies in the proposed rule generally would take effect on January 1, 2016. **The 60-day comment period ends at close of business on September 8, 2015.**

The proposed rule would update the PFS payment policies that apply to services furnished by physicians and other practitioners in all sites of services. In addition to physicians, the PFS pays a variety of practitioners and entities, including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities. The proposed rule also includes updates and refinements to the requirements for the PFS quality programs, including the Medicare EHR Incentive Program, the Physician Quality Reporting System, and the Value-Based Payment Modifier. In addition to proposed policies, CMS requests information about several provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

In the proposed rule, CMS estimates that the conversion factor (CF) under the PFS for the 2016 would be $36.1096 (compared to the current 2015 conversion factor of $35.9335). This estimate is based upon a 0.5 percent update factor specified under MACRA and the adjustments necessary to maintain budget neutrality for the policies in this proposed rule. This estimate does not incorporate the Protecting Access to Medicare Act of 2014 (PAMA) provision that establishes an annual target reduction in PFS expenditures resulting from adjustments to relative values of misvalued codes for 2017 through 2020. If the net reductions in misvalued codes in 2016 are not ≥ 1 percent of the estimated expenditures under the fee schedule, a reduction equal to the percent difference between 1 percent and the estimated net reduction in expenditures resulting from misvalued codes must be made to all PFS services. CMS estimates, the net reduction in expenditures will be 0.25 percent as a result of proposed adjustments to the relative value established for misvalued codes in this proposed rule. CMS could, however, make further misvalued code changes in the final rule.

On a specialty-specific basis, CMS estimates that the combined impact of the proposed rule would have the greatest negative effect on radiation oncology (-3 percent), gastroenterology (-5

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\(^1\) Henceforth in this document, a year is a calendar year unless otherwise indicated.
percent), and radiation therapy centers (-9 percent) and the greatest positive effect on pathology (+8 percent) and independent laboratories (+9 percent).

The addenda to the proposed rule along with other supporting documents are again only available through the Internet at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html).

II. Provisions of the Proposed Rule for PFS

A. Determinations of 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.

For 2016, CMS makes note of several issues in this section.

CMS incorporates the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014. CMS proposes to use a proxy practice expense per hour (PE/HR) value for interventional cardiology, as there are no data for this specialty from the Physician Practice Expense Information Survey, by crosswalking the PE/HR from Cardiology. CMS notes the specialties furnish similar services based on its review of Medicare claims data.

CMS proposes a modification to Step 7 of its PE RVU methodology: calculation of direct and indirect PE percentages at the service level, which takes a weighted average of the specialties that furnish the service. Historically, CMS has used the specialties that furnish the service in the most recent full year of Medicare claims data (crosswalked to the current year set of codes) to determine which specialties furnish individual procedures. For example, for 2015 ratesetting, CMS used the mix of specialties that furnished the services in the 2013 claims data to determine the specialty mix assigned to each code. To create more stability and mitigate code-level fluctuations, particularly for new and low-volume codes, CMS proposes to refine this step of the PE methodology to use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code.

With respect to the formula for calculating equipment cost per minute, CMS notes that it solicited comments in 2015 rulemaking on whether the maintenance factor should be variable rather than the current, uniform 0.05. CMS notes that the data it received were limited and may not reflect typical costs. Thus, CMS continues to seek a source of publicly available data on actual maintenance costs for medical equipment to improve the accuracy of the equipment costs used in developing PE RVUs. CMS does not propose any changes to the factor for maintenance in 2016.
2. Changes to Direct PE Inputs for Specific Services

a. PE Inputs for Digital Imaging Services

CMS notes that in 2015 it proposed and finalized its proposal to remove the film supply and equipment items, and to create a new equipment item as a proxy for the PACS workstation as a direct expense. Thus, CMS proposes to update the price for the PACS workstation to $5,557 from the current price of $2,501 since the latter price was based on the proxy item and the former based on submitted invoice. These invoices were received from one stakeholder.

CMS also notes that in addition to the workstation used by the clinical staff acquiring the images and furnishing the technical component of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the professional component of many of these services. CMS notes that it generally believes that workstations used by practitioners are more accurately considered indirect costs associated with the professional component of the service, but that the professional workstations for interpretation of digital images are similar in principle to the previous film inputs. **CMS invites comment on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes (consistent with its established methodology).**

CMS also seeks comment from stakeholders, including the RUC, about whether or not the PACS workstation used in imaging codes is the same workstation that is used in the postprocessing described by CPT code 76377 (3d render w/intrp postproces), or if more specific workstation should be incorporated in the direct PE input database.

b. Standardization of Clinical Labor Tasks

CMS states that it continues to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. CMS believes that by doing so, this will increase the transparency of the information used to set PE RVUs, facilitate the identification of exceptions to the usual values, provide greater consistency among codes that share the same clinical labor tasks, and improve relativity of values among codes. In addition, CMS notes the advantage that as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In this rule, CMS specifically seeks comment on clinical labor tasks associated with digital imaging and pathology clinical labor tasks, and proposes eliminating the minutes assigned for “complete Botox log”.

With respect to clinical labor tasks associated with digital imaging, CMS believes it would be appropriate to establish standard times for clinical labor tasks associated with all digital imaging
for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the database facilitate its ability to adjust time for existing services. **CMS invites comment on the appropriate standard minutes for clinical labor tasks associated with services that use digital technology** (listed in Table 5 of the proposed rule and reproduced below).

**TABLE 5: Clinical Labor Tasks Associated with Digital Technology**

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<tr>
<th>Clinical Labor Task</th>
<th>Typical Minutes</th>
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<tr>
<td>Availability of prior images confirmed</td>
<td>2</td>
</tr>
<tr>
<td>Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist.</td>
<td>2</td>
</tr>
<tr>
<td>Technologist QC’s* images in PACS, checking for all images, reformats, and dose page.</td>
<td>2</td>
</tr>
<tr>
<td>Review examination with interpreting MD</td>
<td>2</td>
</tr>
<tr>
<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>1</td>
</tr>
</tbody>
</table>

*This clinical labor task is listed as it appears on the “PE worksheets.” QC refers to quality control, which CMS understands to mean the verification of the image using the PACS workstation.

With respect to pathology clinical labor tasks, CMS notes that many of the specialized clinical labor tasks associated with pathology services do not have consistent times across those codes, and the information CMS has reviewed does not support these inconsistencies. CMS developed proposed standard times for 17 pathology clinical labor tasks based on its review and assessment of the current times included for these clinical labor tasks in the direct PE input database (listed in Table 6). The standard clinical labor times assigned range from one-half of a minute to assemble and deliver slides with paperwork to pathologists to 13 minutes for instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling. **CMS invites comment on whether these standard times accurately reflect the typical time it takes to perform these clinical labor tasks when furnishing pathology services.**

CMS also proposes to eliminate the minutes assigned for the task “complete botox log” from the direct PE input database, as completion of such a log is not a direct resource cost of furnishing a medically reasonable and necessary physician’s service for a Medicare beneficiary

c. **Clinical Labor Input Inconsistencies**

CMS proposes to correct clerical inconsistencies related to several vertebroplasty codes. For CPT codes 22510 (percutaneous cervicothoracic injection) and 22511 (percutaneous lumbosacral injection) CMS proposes 34 minutes (note that proposed text is unclear, but the PE database lists 34 minutes) for labor code L041B (“Radiologic Technologist”) for the “assist physician” task.
and a value of 5 minutes for labor code L037D (‘RN/LPN/MTA’) for the “Check dressings & wound/ home care instructions /coordinate office visits /prescriptions” task. CMS proposes for CPT code 22514 (percutaneous vertebral augmentation) to adjust the nonfacility intraservice time to 50 minutes for L041B, 50 minutes for L051A (“RN”), 38 minutes for a second L041B, and 12 minutes for L037D.

d. **Freezer**

CMS identified several pathology codes for which equipment minutes are assigned to item EP110 “Freezer” as a direct cost. Instead, CMS proposes to classify the freezer as an indirect cost because it believes that this would be more consistent with the principles underlying the PE methodology given that freezers can be used for many specimens at once.

e. **Updates to Price for Existing Direct Inputs**

In response to requests received in 2014, CMS proposes to create a new supply code for Spherusol, valued at $590 per 1 ml vial and $59 per test, and to include this new item as a supply for 86490 instead of the current input, SH006. CMS also proposes to increase the price for EQ340 (Patient Worn Telemetry System) used only in CPT code 93229 (remote 30 day ecg tech sup) from $21,575 to $23,537 to account for the equipment costs specific to the patient-worn telemetry system. CMS notes that it considered this request in the context of the unique nature of this particular equipment item that is it used continuously 24 hours per day and 7 days per week for an individual patient over several weeks and that it is primarily used outside of a healthcare setting. CMS notes that in 2015 it received a request to update the price for supply item “kit, HER–2/neu DNA Probe” (SL196) from $105 to $144.50, but chose not do so because it found readily available information from its research suggesting that the $144.50 was too high. One stakeholder suggested that the lower price found by CMS was based on volume discounts and not typical. CMS invites comment on how to consider the higher-priced invoice and seeks information on the price of the disposable supply in the typical case of the service furnished to a Medicare beneficiary, including, based on data, whether the typical Medicare case is furnished by an entity likely to receive a volume discount.

f. **Typical Supply and Equipment Inputs for Pathology Services**

CMS notes its concern, expressed in 2013 and 2015 rulemaking, about the typical number of pathology tests furnished at once, which significantly affects the assumed clinical labor, supplies, and equipment for that service. CMS is soliciting stakeholder input on obtaining more accurate information for both pathology services and more broadly for services across the PFS.

g. **Request for Information on Nonfacility Cataract Surgery**

CMS notes that cataract surgery generally has been performed in an ambulatory surgery center (ASC) or a hospital outpatient department (HOPD), and thus CMS has not assigned nonfacility PE RVUs under the PFS for cataract surgery. CMS believes that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases, and may offer beneficiaries additional benefits such as the convenience of receiving the preoperative, operative,
and post-operative care in one location. CMS also notes that offering this service in the office setting for certain cases may also reduce Medicare expenditures.

CMS invites comments from ophthalmologists and other stakeholders on office-based surgical suite cataract surgery on this proposal. In addition, CMS is soliciting comments from the RUC and other stakeholders on the direct practice expense inputs involved in furnishing cataract surgery in the nonfacility setting in conjunction with consideration of information regarding the possibility of developing nonfacility PE RVUs for cataract surgery.

h. Direct PE Inputs for Functional Endoscopic Sinus Surgery Services

CMS received comments indicating that due to changes in technology and technique, several codes that describe endoscopic sinus surgeries can now be furnished in the nonfacility setting. CMS seeks input from stakeholders, including the RUC, about the appropriate direct PE inputs for these 7 endoscopic sinus surgery services (CPT codes 31254, 31255, 31256, 31267, 31276, 31287, and 31288).

B. Determination of Malpractice Relative Value Units (MP RVUs)

1. Proposed Annual Update of MP RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and malpractice (MP) expense. As way of background, the resource-based formula to determine the malpractice for a given service is comprised of three major components: (1) specialty’s risk factor, (2) specialty weight—or the mix of practitioners providing the service—compared to all other specialties, and (3) work value for the service. In 2015, CMS implemented the third comprehensive five-year review and update of MP RVUs, which updated each specialty’s risk factor based upon updated premium data. CMS proposes to continue its current approach for determining MP RVUs for new/revised codes. That is, the MP crosswalks for new and revised codes with interim final values established in the 2016 final rule will be implemented for 2016 and subject to public comment. They will then be finalized in the 2017 PFS final rule with comment period.

For 2016, CMS proposes to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services, and to adjust MP RVUs for risk. Under this approach, the specialty-specific risk factors would continue to be updated every five years using updated premium data and would remain unchanged between the 5-year reviews. However, in an effort to ensure that MP RVUs are as current as possible, the CMS proposal would involve recalibrating all MP RVUs on an annual basis to reflect the specialty mix based upon updated Medicare claims data.

CMS also proposes to maintain the relative pool of MP RVUs from year to year to preserve the relative weight of MP RVUs to work and PE RVUs. CMS proposes to determine the specialty mix assigned to each code using the same process used in the PE methodology. This would include the CMS proposal to use the 3 most recent years of
available data instead of a single year of data, as is its current policy, to determine the
specialty mix. CMS also proposes to no longer apply the dominant specialty for low
volume services, because the primary rationale for the policy has been mitigated by this
proposed change in methodology. CMS, however, plans to maintain the code-specific
overrides established in prior rulemaking for codes where the claims data are inconsistent
with a specialty that could be reasonably expected to furnish the service.

CMS seeks comment on both aspects of the proposal: updating the specialty mix for
MP RVUs annually (while continuing to update specialty-specific risk factors every
5 years using updated premium data); and using the same process to determine the
specialty mix assigned to each code as is used in the PE methodology, including the
proposed modification to use the most recent 3 years of claims data. CMS also seeks
comment on whether this approach will be helpful in addressing some of the
concerns regarding the calculation of MP RVUs for services with low volume in the
Medicare population, including the possibility of limiting the use of code-specific
overrides of the claims data.

Finally, CMS proposes an additional refinement in its process for assigning MP RVUs to
add-on codes. Specifically, CMS proposes to maintain the 0.01 MP RVU floor for all
nationally-priced PFS services that are described by base codes, but not for add-on codes.
Under current policy, CMS notes that by applying the floor to add-on codes, the current
methodology practically creates a 0.02 floor for any service reported with one add-on
code. CMS states that it will continue to calculate, display, and make payments that
include MP RVUs for add-on codes that are calculated to 0.01 or greater, including those
that round to 0.01. CMS is only proposing to allow the MP RVUs for add-on codes to
round to 0.00 where the calculated MP RVU is less than 0.005.

2. MP RVU Update for Anesthesia Services

CMS notes that in the 2015 PFS proposed rule, it did not include an adjustment under the
anesthesia fee schedule to reflect updated MP premium information, and stated that it
intended to propose an anesthesia adjustment for MP in the 2016 PFS proposed rule. For
2016, CMS proposes to make adjustments to the anesthesia conversion factor to reflect
the updated premium information collected for the five year review. To determine the
appropriate adjustment, CMS calculated the imputed work RVUs and MP RVUs for the
anesthesiology fee schedule services using the work, PE, and MP shares of the anesthesia
fee schedule. CMS provides the detailed steps required to calculate the MP RVUs
for anesthesia service, and invites comments on this proposal.

3. MP RVU Methodology Refinements

CMS proposes two technical refinements to how it calculates MP RVUs. First, CMS identified a
necessary refinement to the way it computed a preliminary national average premium for each
specialty to align with how the calculations was described within the contractors report
(published as part of the 2015 rulemaking, “Final Report on the CY 2015 Update of
Malpractice RVUs”). The calculation currently takes the ratio of sums, rather than the weighted average of the local premiums to the MP GPCI in that area. Instead, CMS proposes to update the calculation to use a price-adjusted premium (that is, the premium divided by the GPCI) in each area, and then take a weighted average of those adjusted premiums. Second, in the calculation of the national average premium for each specialty, CMS’ current methodology uses the total RVUs in each area as the weight in the numerator (that is, for premiums), and total MP RVUs as the weights in the denominator (that is, for the MP GP CiS). After further consideration, CMS believes these weights are problematic (circularity problem) as both weights incorporate MP RVUs as part of the computation to calculate MP RVUs. CMS proposes, instead, a different measure that is independent of MP RVUs as a weight: area population as a share of total U.S. population.

C. 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 ongoing 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. The Urban project plans to convene groups of physicians from a range of specialties to review the new time data and the potential implications for work and the ratio of work to time. CMS reports that the Urban Institute prepared an interim report, “Development of a Model for the Valuation of Work RVUs” which discusses the challenges Urban encountered collecting data. CMS plans to make the final report available on the CMS website.

The second contract, with the RAND Corporation, used available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity, and identify potentially misvalued procedures. The RAND report is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC.

2. CY 2016 Identification and Review of Potentially Misvalued Services

a. Public Nomination

During the comment period for the 2015 PFS final rule, CMS received nominations and supporting documentation for three codes: CPT codes 36516, 52441 and 52442.

- CPT code 36516 (Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion). The nominator stated that the direct supply costs failed to include costs for a disposable bag and for biohazard waste disposal of the post-treatment bag, and the labor costs for the associated nursing services were inaccurate. The nominator was also concerned about the associated overhead expenses and the work RVUs. CMS is proposing this code as a potentially misvalued code. CMS
notes that biohazard bags are considered indirect PE and not as a direct PE input (75FR 73192).

- CPT codes 52441 (Cystourethroscopy with insertion of transprostatic implant; single implant) and 52442 (Cystourethroscopy with insertion of transprostatic implant; each additional implant). The nominator stated that the cost of the direct practice inputs were inaccurate, including the costs of the implant. CMS is proposing these codes as potentially misvalued codes.

b. Electronic Analysis of Implanted Neurostimulator (CPT codes 95970-95982)

In the 2015 final rule, CMS reviewed and valued three of the codes in this family (CPT codes 95971, 95972, and 95973). Based on significant time changes in the base codes, CMS is concerned the entire family is potentially misvalued and proposes to review the codes listed in Table 7 (CPT codes 95970, 95974, 95975, 95978 – 95982).

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

Section 220(c) of PAMA expanded the list of categories of codes the Secretary is directed to examine and included codes that account for the majority of spending under the PFS. Table 8 lists the 118 codes identified through the high expenditure specialty screen. CMS used the same approach established in 2015 except they excluded codes with 10 and 90-day global periods. Specifically, CMS identified the top 20 codes by specialty (using the specialties in Table 45) in terms of allowed charges. They excluded codes that have been reviewed since 2010, codes with fewer than $10 million in allowed charges, and codes that describe anesthesia or E/M services.

3. 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 400 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 indicates that a separate anesthesia service is reported more than 50 percent of the time when several different types of colonoscopy procedures are reported. In the 2015 proposed rule, CMS solicited public comment on approaches to address the appropriate valuation of these services.

CMS is considering establishing a uniform approach to valuation for all Appendix G services for which moderate sedation is no longer inherent, rather than addressing this issue at the procedure level as individual procedures are revalued. **CMS seeks recommendations from the RUC and other interested stakeholders on approaches to address the appropriate valuation of the**
work associated with moderate sedation. CMS is proposing to identify CPT codes 00740 (Anesthesia for procedure on GI tract using an endoscope) and 00810 (Anesthesia for procedure on lower intestine using as endoscope) as potentially misvalued codes.

4. Improving the Valuation and Coding of the Global Package

In 2015, CMS finalized a policy to transition all 10-day and 90-day global codes to 0-day global codes. Section 523 of MACRA, enacted into law on April 16, 2015, prohibits the Secretary from implementing this policy established in the 2015 final rule (Section 1848(c)(8)(A)(i) of the Act). The Secretary, however, is not prevented from revaluing specific surgical services as misvalued codes or assigning values to new or revised codes for surgical services.

Section 1848(c)(8)(B)(i) of the Act requires CMS to use rulemaking to obtain information needed to value surgical services from a representative sample of physicians and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery, as appropriate; the information must be reported on claims or in another manner specified by the Secretary. The Secretary is also authorized through rulemaking, to delay up to 5 percent of the PFS payment for services, which a physician is required to report information until the required information is reported. Beginning in 2019, the information collected, along with other available date, must be used to improve the accuracy of the valuation of surgical services (Section 1848(c)(8)(C)) of the Act.

CMS seeks specific comments on how to efficiently obtain auditable, objective data to:
- Determine the number and level of post-operative E/M visits furnished during the current post-operative periods. CMS also seeks information on the extent to which individual physicians or practices may currently maintain their own data on services furnished during the post-operative period, and how CMS might collect and objectively evaluate this data.
- Revalue the individual components of the global surgical package, including the procedure and the pre-and post-operative care. CMS states they are particularly interested in input regarding the overall accuracy of the values and descriptions of the component services within the global packages. In addition to information on the post-operative E/M services, CMS is interested in input on other items and services related to surgery and are furnished to beneficiaries during post-operative care.

CMS will use the input from public comments to help develop a proposed approach for the collection of this information in future rulemaking. CMS is also seeking comments regarding stakeholder’s interest in open door forums, town hall meetings or other means for direct communication about these issues.

D. Refinement Panel

Beginning in 2016, CMS is proposing to permanently eliminate the refinement panel. With the change in the process for valuing codes adopted in the 2015 final rule, CMS believes that there will only be a limited number of codes being valued for 2016 that will be published as
interim final in the 2016 final rule and be subject to comment (see discussion below in section I 2). For these codes with interim final values, CMS plans to evaluate the comments they receive and respond to comments and propose values for these codes for 2017 in the 2017 proposed rule; comments would also be allowed in response to the 2017 proposed rule. CMS believes this proposed process, with two opportunities for notice and comment, offers stakeholders a better mechanism for providing additional data than the current refinement process and allows greater transparency because comments are available to the public (www.regulations.gov).

E. Improving Payment Accuracy for Primary Care and Care Management Services

CMS discusses input they have received from stakeholders that the current E/M office/outpatient visit CPT codes do not reflect all the services and resources involved with furnishing comprehensive, coordinated care management for certain categories of beneficiaries. As discussed below, CMS solicits public comment on several issues related to recognizing all the different resources used in providing this type of care.

1. Improved Payment for the Professional Work of Care Management Services

CMS notes that stakeholders assert that there is more cognitive work that primary care physicians and other practitioners perform in planning and thinking critically about the individual chronic needs of particular subsets of Medicare beneficiaries that are in addition to the work typically required to supervise and manage the clinical staff associated with the current transitional care management (TCM) and chronic care management (CCM) codes.

CMS seeks specific comments on ways to recognize the different resources (particularly cognitive work) involved in delivering comprehensive, coordinate care management beyond those resources involved in the current codes. Issues include:

- The time and intensity related to the management of both long-term and episodic conditions.
- Codes that could be used in addition to, not instead of, the current E/M codes. CMS discusses the current use of existing add-on codes that describe additional resource costs (i.e. additional slides in pathology services or additional complexity in psychotherapy services). CMS notes that codes might be used to allow for the reporting of additional work by “primary care and other cognitive specialties” in conjunction with an E/M service. CMS provides an example of an add-on code that could describe the professional time in excess of 30 minutes and/or a certain set of furnished services, per one calendar month for a single patient to coordinate care, provide patient or caregiver education, reconcile and manage medications, assess and integrate data or develop and modify care plans.
- Whether or not there is overlap between these additional cognitive resources described by stakeholders and the current cognitive resources that are accounted for the current CCM and other care management services.

CMS notes that if they include add-on codes they would require an established relationship between the patient and the billing professional. CMS also notes that the add-on codes might apply broadly to patients in a number of different circumstances and they would not make
reporting the codes contingent on a particular business model or technology. CMS anticipates developing potential proposals to address these issues through rulemaking in 2016 for implementation in 2017.

2. Establishing Separate Payment for Collaborative Care

CMS believes that the care management for Medicare beneficiaries with multiple chronic conditions or common behavioral conditions can require extensive discussion, information sharing and planning between a primary care physician and a specialist (e.g. a neurologist for a patient with Alzheimer’s disease and other chronic diseases). CMS acknowledges that in 2014, CPT created four codes that describe interprofessional telephone/internet consultative services (CPT codes 99446-99449) but that CMS does not make separate payment for these services as they are considered part of other services furnished to beneficiaries.

**CMS seeks specific comments** on ways to more accurately account for the resource costs of a more robust interpersonal consultation involved for care coordination for patients requiring more extensive care. Issues include:

- Are there specific conditions where it might be appropriate to make separate payment for services similar to those described in the CPT codes?
- The parameters for providing these services and resources involved in collaborations between a specialist and a primary care practitioner, especially in the context of the current E/M services.
- How these collaborations would be distinguished from the kind of services already included in other E/M services.
- Should these interprofessional consultations be linked with a beneficiary encounter? CMS seeks input on how to develop appropriate beneficiary protections to ensure that beneficiaries are aware of the involvement of the specialist prior to being billed for services.
- Is there key technology needed to support collaboration between specialists and primary care practitioners and should technology requirements be included as part of the service?

CMS is also interested in whether this kind of benefit might be included in a CMMI model that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variations in payment amounts for the specialist and primary care practitioners. CMS anticipates developing potential proposals to address these issues through rulemaking in 2016 for implementation in 2017.

**Collaborative Care Models for Beneficiaries with Common Behavioral Health Conditions**

Because there is documented evidence, including randomized controlled trials, for providing collaborative care for patients with common behavior conditions, CMS is interested in obtaining information about how this specific model could be coded and reimbursed under the PFS. Collaborative care typically is provided by a primary care team, consisting of a primary care provider and a care manager, working in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with a regular assessment of clinical status and treatment modifications. The psychiatric
consultant reviews the clinical status and care plan and provides regular consultations to the primary care team.

**CMS seeks specific comments on ways to refine the PFS to provide coding and reimbursement for this collaborative care model.** Additional issues include:

- Are there other diagnosis and treatment modalities that are treated through a collaborative care model?
- Should CMS establish a code similar to the CCM code that would be applicable to collaborative care and other interprofessional services?
- Should a code for collaborative care have requirements similar to those used for CCM services and could collaborative care be reported in conjunction with CCM or other E/M services?
- Should the psychiatric consultant be required to have written consent from the beneficiary for the non-face-to-face services before the services are billed?
- Is there key technology needed to support collaboration between specialists and primary care practitioners and should technology requirements be included as part of the service?

Similar to the broader concept of collaborative care, CMS is also interested in whether this kind of care model should be implemented through a CMMI demonstration that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variations in payment amounts for the psychiatric consultant and the primary care practitioner. CMS anticipates developing potential proposals to address these issues through rulemaking in 2016 for implementation in 2017.

3. CCM and TCM Services

CMS implemented separate payment for TCM services in 2013 and for CCM services in 2015. CMS acknowledges that there are more extensive requirements for TCM and CCM than for other E/M services and that some practitioners have stated that the service elements and billing requirements are too burdensome and interfere with their ability to provide these services. **CMS solicits comments on ways to improve beneficiary access to TCM and CCM services.**

CMS is seeking information about the utilization of CCM codes to help inform any changes in payment and coding that may be proposed in future rulemaking. CMS seeks information on:

- The clinical status of beneficiaries receiving the services.
- The resources involved in furnishing these services, such as the number of documented non-face-to-face minutes furnished by clinical staff in the month the code is reported.
- Objective data about the resource costs associated with furnishing CCM.

**F. Target for Relative Value Adjustments for Misvalued Services**

PAMA added a new subparagraph at section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under this provision, if the estimated net reduction in expenditures for a year is equal to or greater than the target for the year, then these adjustments would be redistributed in a budget-neutral manner within the PFS. If net reduction in expenditure is greater than the target then the
difference is applied to the next year for purposes of meeting that year’s target. On the other hand, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, then the amount equal to the target recapture amount or the difference between the target and the amount of expenditures reduced would not be applied in a budget neutral manner. Section 220(d) of the PAMA applied to 2017 through 2020 and set the target under section 1848(c)(2)(O)(v) of the Act at 0.5 percent of the estimated amount of expenditures under the PFS for each of those 4 years. These target amounts were subsequently revised by Section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE), which accelerated the application of the PFS expenditure reduction target to 2016, 2017, and 2018, and to set a 1 percent target for 2016 and 0.5 percent for 2017 and 2018.

CMS proposes a methodology to implement this statutory provision in a manner consistent with the broader statutory construct of the PFS. In developing this proposed methodology, CMS has identified several aspects of its approach, which are discussed in more detail below. CMS seeks comment on these aspects and all aspects of its proposal.

1. Distinguishing “Misvalued Code” Adjustments from Other RVU Adjustments

CMS notes that the potentially misvalued code initiative has resulted in changes in PFS payments in several ways. First, potentially misvalued codes have been identified, reviewed, and revalued through notice and comment rulemaking. In many cases, the identification of particular codes as potentially misvalued has led to the review and revaluation of related codes, and frequently, to revisions to the underlying coding for large sets of related services (e.g., revising the direct PE inputs for imaging services to assume digital instead of films costs). CMS also notes that changes in input values to potentially misvalued codes has a broader impact on input values for all codes in the PFS due to the relativity inherent in the PFS ratesetting process and the budget neutrality requirements.

CMS considered several options to identifying a subset of the adjustments in RVUs for a year to reflect an estimated “net reduction” in expenditures, necessary to implement the PFS expenditure reduction target provisions. The options CMS considered in calculating the estimated net reduction in PFS were the following: (1) including all changes in RVUs for a year (would include budget neutrality adjustments), (2) limiting the calculation to reflect RVU adjustments made to the codes formally identified as “potentially misvalued, (3) including only those codes that underwent a comprehensive review (work and PE), and (4) including adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values.

After considering these options, CMS believes the best approach is to define the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values. This would limit the pool of RVU adjustments used to calculate the net reduction in expenditures to those services for which individual, comprehensive review or broader proposed adjustments have resulted in changes to service-level inputs of work RVUs, direct PE inputs, or MP RVUs, as well as services directly affected by changes to coding for related services.

CMS notes concerns about how best to account for changes from one year to the next given that
2015 was the final full year of establishing interim final values for all new, revised, and potentially misvalued codes. CMS explains that the overall change in valuation for many misvalued codes is measured across values for 3 years, with most of the reduction in values occurring between years 1 and 2, whereas changes from years 2 and 3 tend to be no change or even an increase in values. As a result, CMS notes that including changes that take place over 3 years is particularly problematic for calculating the target for 2016 for two reasons. First, 2015 was the final full year of establishing interim final values for all new, revised, and potentially misvalued codes. Starting with this proposed rule, CMS proposes and finalizes values for a significant portion of misvalued codes during one calendar year. Therefore, 2015 will include a disproportionate number of services that would be measured between years 2 and 3 relative to the services measured between 1 and 2 years.

Thus, CMS proposes to exclude code-level input changes for 2015 interim final values from the calculation of the 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision. CMS also notes that the impact of interim final values in the calculation of targets for future years will be diminished as CMS transitions to proposing values for almost all new, revised, and potentially misvalued codes in the proposed rule.

2. Calculating “Net Reduction”

CMS proposes to net the increases and decreases in values for services, including those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes. CMS considered the possibility of ignoring the applicable increases in valuation in the calculation of net reduction. However, CMS believes that the requirement to calculate “net” reductions implies that it takes into consideration decreases and increases, and that this approach may be the only practical one due to the presence of new and deleted codes on an annual basis.

3. Measuring the Adjustments

CMS proposes to use the approach of comparing the total RVUs (by volume) for the relevant set of codes in the current year to the update year, and divide that result by the total RVUs (by volume) for the current year. CMS notes that this is the most straightforward approach and it is intuitive and relatively easy to replicate and provided similar estimated net reductions to an alternative and more complex and precise approach CMS discussed. CMS explained that a more precise method would need to compare, for the included codes, the update year’s total work RVUs (by volume), direct PE RVUs (by volume), indirect PE RVUs (by volume), and MP RVUs (by volume) to the same RVUs in the current year, prior to the application of any scaling factors or adjustments. CMS also notes that this approach would be more difficult to replicate and CMS experienced methodological challenges in making these calculations.

CMS seeks comment on whether comparing the update year’s work RVUs, direct PE RVUs, indirect PE RVUs, and MP RVUs for the relevant set of codes (by volume) prior to the application of any scaling factors or adjustments to those of the current year would be a preferable methodology for determining the estimated net reduction.

CMS notes that it will not incorporate the impact of the target into the calculation of the proposed PFS payment rates for 2016, unlike for the targets for 2017 and 2018, because it was not able to calculate a realistic estimate of the target amount at the time the proposed rule was published. CMS further explains that in 2016 there will still be a significant number of codes valued not in the proposed rule but in the final rule with comment period. In future years (with the exception of entirely new services), all codes, even those for which CMS does not receive RUC recommendations in time for the proposed rule, will be in the proposed rule for the subsequent year and not in the final rule with comment period.

CMS refers readers to the regulatory impact section of the proposed rule for an interim estimated net reduction in expenditures relative to the 1 percent target for 2016, based solely on the proposed changes in this rule. CMS estimates that the net reduction is approximately 0.25 percent of the estimated amount of expenditure under the fee schedule for 2016. This would imply (though not explicitly stated by CMS) that if this interim estimate held true without any other adjustments (unlikely due to the significant number of codes to be values in the final rule) CMS would need to reduce the conversion factor by 0.75 percent.

G. Phase-in of Significant RVU Reductions

Section 1848(c)(7) of the Act, added by PAMA, also specifies that for services that are not new or revised codes, applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. The ABLE Act amended section 1848(c)(7) of the Act to require that the phase-in begin for 2016 rather than 2017, as specified by PAMA.

CMS proposes a methodology to implement this statutory provision and identified several aspects of its approach for which it is specifically seeking comment.

Identifying Services that are Not New or Revised Codes: The statute specifies that services described by new or revised codes are not subject to the phase-in of RVUs. This recognizes that there is no practical way to phase-in over 2 years changes to RVUs that occur as a result of a coding change for a particular service because there is no relevant reference code or value on which to base the transition. To determine which services are described by new or revised codes for purposes of the phase-in provision, CMS proposes to apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and to exclude codes that describe different services in the current and update year. CMS also notes that it would exclude from the phase-in as new and revised codes those codes with changes to the global period, since the code in the current year would not describe the same units of service as the code in the update year.
Estimating the 20 Percent Threshold: With respect to estimating the 20 percent threshold, CMS proposes to estimate total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. Thus, it is possible that some codes may not qualify for the phase-in despite a reduction in RVUs that are slightly higher 20 percent due to budget neutrality adjustments.

RVUs in the First Year of the Phase-In: CMS describes two approaches to determine the portion of the reduction to be phased-in for the first year. The first option, commonly used by CMS, for a two-year transition would be a 50 percent phase-in of the reduction in the first year and a 50 percent reduction in the second year. CMS expressed concern that this approach has a significant drawback. A service that is estimated to be reduced by a total of 19 percent for an update year would be reduced by a full 19 percent in that update year, while a service that is estimated to be reduced by 20 percent in an update year would only be reduced 10 percent in that update year. After consideration, CMS proposes to consider the 19 percent reduction as the maximum 1-year reduction and to phase-in any remaining reduction greater than 19 percent in the second year of the phase-in. CMS seeks comment on this proposal.

Applicable Adjustments to RVUs: CMS notes that the most straightforward and fair approach to addressing both the site of service differential and the codes with professional and technical components is to consider the RVUs for the different sites of service and components independently for purposes of identifying when and how the phase-in applies. CMS proposes therefore, to estimate whether a particular code meets the 20 percent threshold for change in total RVUs by taking into account the total RVUs that apply to a particular setting or to a particular component. In addition, since variation of PE RVUs is the only constant across all individual codes, codes with site of service differentials, and codes with professional and technical components, CMS proposes to apply all adjustments for the phase-in to the PE RVUs. The list of 48 codes subject to the phase-in, and the RVUs that result from this proposed methodology, is available on the CMS website under downloads for the 2016 PFS proposed rule with comment period http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-P.html.

H. Changes for Computed Tomography (CT) under the Protecting Access to Medicare Act of 2014 (PAMA)

CMS proposes to implement section 281(a)(1) of PAMA which requires a reduction in payment amounts under the PFS and the hospital outpatient prospective payment system (OPPS) for the technical component of computed tomography (CT) for services furnished using equipment that fails to meet each of the attributes of NEMA Standard XR-29-2013 (entitled “Standard Attributes on CT Equipment Related to Dose Optimization and Management”). The specific CT services are identified by the following CPT codes: 70450-70498, 71250-71275, 72125-72133, 72191-72194, 73200-73206, 73700-73706, 74150-74178, 74261-74263, 75571-75574, and any succeeding codes.

Beginning in 2016, claims will need to be submitted with the modifier “CT” (CT, services furnished using equipment that does not meet each of the attributes of the NEMA SR-29-2013 standard). Payment for the technical component (TC) (and the TC of the global fee) of the PFS
and OPPS would be reduced by 5 percent in 2016 and 15 percent in 2017. Any reduced expenditures from this provision are not budget neutral.

I. Valuation of Specific Codes

1. Process for Valuing New, Revised, and Potentially Misvalued Codes

In the 2015 final rule, CMS finalized a new process for establishing values for new, revised, and potentially misvalued codes. Under the new process, CMS will include proposed values for these codes in the proposed rule, instead of establishing them as interim final in the final rule.

CY 2016 is a transition year for the new process.

- In this proposed rule, CMS is proposing new values for codes for which they received RUC recommendations by February 10, 2015. CMS will consider all comments received in response to proposed values in this rule and will develop final values for these codes in the 2016 final rule.
- For recommendations regarding any new or revised codes received after the February 10, 2015 deadline, including updated recommendations for codes included in this proposed rule, CMS will establish interim final values in the final rule. This is consistent with the previous practice.

Beginning with 2017, the new process will apply to all applicable codes.

- CMS will propose values for the vast majority of new, revised and potentially misvalued codes and consider public comments before establishing final values for the codes.
- For codes where CMS does not receive a RUC recommendation by February 10th, CMS would delay revaluing the code for one year and include proposed values in the following year’s rule.
- CMS will 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.
- CMS will 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.

CMS notes that for 2016, they received RUC recommendations prior to February 10, 2015 for many new, revised and potentially misvalued codes and this rule includes proposed values for these codes. CMS notes, however, that the RUC recommendations included CPT tracking codes (these codes usually have 6 or 7 characters) instead of the actual 2016 CPT codes (5 characters). Because the CMS systems only utilize 5-character HCPCS codes, CMS developed alternative 5 character placeholder codes for this rule and the final CPT codes will be included in the final rule. A crosswalk from the 5-character placeholder codes to the CPT tracking codes is available at http://www.cms.gov/physicianfeesched/downloads/.
2. Establishing RVUs for 2016 for New, Revised and Potentially Misvalued Codes

CMS reviewed the RUC recommendations for work RVUs and direct PE inputs for new, revised, and potentially misvalued codes. For determining malpractice (MP) RVUs, CMS used their established malpractice methodology which uses a cross walk to establish risk factors for new services. Addendum B of this proposed rule includes the proposed work, practice expense (PE) and malpractice (MP) RVUs for all 2016 payable codes, including codes with proposed changes. Addendum B is available at http://www.cms.gov/physicianfeesched/downloads/. All proposed values are subject to public comment.

Information about specific proposed changes is provided in the following tables included in the proposed rule:

- **Work RVUs.** Table 11 contains a list of proposed work RVUs for all new, revised and potentially misvalued codes (128 codes) with RUC recommendations received by February 10, 2015. Proposed work RVUs that vary from those recommended by the RUC or which do not have RUC recommendations are discussed in detail in the proposed rule.

- **Direct Practice Expense.** The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised and potentially misvalued codes. When a RUC recommendation includes supplies or equipment not in the direct PE input database, the RUC generally recommends a new item be created and works with the specialty societies to provide invoice information.
  - Table 9 contains invoices received for new direct PE inputs and Table 10 contains invoices received for existing direct PE inputs. The tables also include the number of invoices received and the number of nonfacility allowed services for procedures that use these items. CMS encourages stakeholders to review these data to determine whether these prices appear to be accurate and when the prices appear inaccurate, they encourage stakeholders to provide invoices or other information to improve the accuracy of these prices. CMS is concerned that a single invoice may not be reflective of typical costs. CMS reminds stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PR RVUs available to all other PFS services. In some cases, CMS does not accept the price listed on the invoice. Proposed PE RVUs that vary from those recommended by the RUC are discussed in detail in the proposed rule.
  - Table 12 contains a list of codes (56 codes) with direct PE input recommendations provided by the RUC and accepted by CMS without any refinement.
  - Table 13 contains CMS’ refinements to the RUC’s direct PE recommendations. CMS notes that for each refinement, they indicate the impact on direct costs for that service; in any case where the impact on the direct cost for a particular refinement is $0.32 or less, the refinement has no impact on the final PE RVUs. CMS notes that nearly half of the refinements listed in Table 13 result in changes under this $0.32 threshold.
• **Malpractice RVUs.** Table 14 lists the crosswalk for establishing 2016 new, revised and potentially misvalued codes (114 codes). The table includes respective source code used to set the proposed 2016 MP RVUs.

In this section, CMS discusses codes that were new or revised in 2015 but CMS either delayed valuing these codes or did not recognize the codes for Medicare purposes. Highlights of this code-specific CMS discussion are summarized below.

a. **Lower Gastrointestinal (GI) Endoscopy Services**

In 2015, CPT revised the lower GI code set and the RUC provided CMS recommendations for valuing these services. In the 2015 final rule, CMS delayed valuing the lower GI codes and indicated they would propose values for these codes in the 2016 proposed rule.

1. **GI Endoscopy (CPT codes 43775, 44380-46607, and HCPCS codes G0104, G0105, and G0121)**

CMS discusses the “incremental difference methodology” that they used in 2014 for valuating the upper GI codes. This methodology uses a base code or another comparable code and considers what the difference should be between that code and another code by comparing the differentials to those for other sets of similar codes. CMS notes that many of the procedures within the colonoscopy subfamily have identical counterparts in the esophagogastroduodenoscopy (EGD) subfamily and discusses the use of the incremental difference methodology for valuing the lower GI endoscopy services. The RUC also used this methodology in valuing many of these codes.

For 2016, CMS reviewed the RUC recommendations for the codes in the lower GI endoscopy family and agreed with several of the RUC recommendations. CMS indicates that disagreements with the RUC are due to CMS’ consistent application of the incremental difference methodology. **Table 15, Application of the Incremental Difference Methodology, provides information about 26 lower GI endoscopy codes including the current work RVUs, RUC recommended RVUs, base procedure, incremental value and calculated work RVUs.**

2. **Laparoscopic Sleeve Gastrectomy (CPT code 43775)**

CMS is proposing to establish national pricing for CPT code 43775, which is currently contractor-priced. **CMS is crosswalking this code to CPT code 37217 and is proposing a work RVU of 20.38 for CPT code 43775.**

3. **Incomplete Colonoscopy (CPT codes 44388, 45378, G0105, and G0121)**

CMS discusses the CPT changes in the definition of an incomplete colonoscopy and the impact on resource uses. Prior to 2015, CPT instructions defined an incomplete colonoscopy as a colonoscopy that did not evaluate the colon past the splenic flexure. According to Medicare instructions, an incomplete colonoscopy was reported with CPT code 45378 with modifier -53 and paid at the same rate as sigmoidoscopy. In 2015, CPT changed the definition of an incomplete colonoscopy to a colonoscopy that does not evaluate the entire colon, including colonoscopies where the colonoscope is advanced past the splenic flexure, but not to the cecum.
and advises reporting 45378 and 44388 with modifier -53 and provide appropriate documentation.

Based on the new CPT definition, CMS believes that CPT code 45378 reported with the -53 modifier will now describe a more resource-intensive group of services that were previously reported and that the crosswalk to the sigmoidoscopy RVUs is not appropriate. **CMS is proposing to develop RVUs for these codes reported with the -53 modifier by using one-half the values of the inputs for the corresponding code reported without the -53 modifier.** In addition, CMS seeks comments on the typical resource costs of these incomplete colonoscopy services under the new CPT definition and the number of incomplete colonoscopies where the scope is not advanced beyond the splenic flexure.

4. **Malpractice (MP) Crosswalk**
CMS notes that the RUC-recommended MP crosswalks for CPT codes 43775, 44407, 44408, 46602 and 46607 are inconsistent with CMS’ analysis of the specialties likely to furnish these services. **CMS proposes using a specialty mix derived from the claims data of the predecessor codes** and when claims data with the new codes is available to incorporate this information into the calculation of the MP RVUs for these services.

**b. Radiation Treatment and Related Image Guidance Services**
In 2015, CPT revised the codes for radiation treatment delivery and the RUC provided CMS recommendations for valuing these services. In the 2015 final rule, CMS delayed valuing these codes and indicated they would propose values for these codes in the 2016 proposed rule.

1. **Image Guidance Services**
Under the previous CPT coding structure, image guidance was separately billable when furnished in conjunction with the radiation treatment delivery services; the image guidance reported depending on which image modality was used (CT, stereotactic, and ultrasound). In the revised coding, one new image guidance code is reported regardless of the modality used.

**CMS agrees with the RUC-recommended work RVUs for the service (CPT code 77387),** which is based on the work RVUs for the new code being roughly prorated, based on the distribution of the predecessor codes in the Medicare claims data. CMS notes that based on the survey data used to value the new code, the RUC recommended an increase in the overall work time associated with image guidance. CMS is concerned that if the survey data is accurate this increase in time and maintenance of total work would suggest a decrease in the overall intensity for image guidance relative to the current codes and seeks comment as to the appropriate work time associated with CPT code 77387.

CMS notes that CPT maintained CPT code 77014 (CT guidance for placement of radiation therapy fields) because this code is necessary for some practitioners to have a valid CPT code alternative than the higher valued diagnostic CT codes when they perform CT guidance. The RUC recommendation indicated that the utilization of this code is expected to drop to negligible levels by 2015. CMS states that they anticipate that CPT and/or the RUC will address the continued use of 77014 and if it continues to be utilized to provide RVU recommendations.
CMS also discusses concerns about the different assumptions used by the CPT editorial panel and the RUC about the new image guidance codes. Specifically, according to CPT, the technical portion of image guidance is now bundled into the IMRT and Stereotactic Radiation Treatment delivery codes but is not bundled into the simple, intermediate and complex radiation treatment delivery codes. The RUC recommendation, however, incorporates the same capital cost of imaging guidance equipment (a linear accelerator or linac) for all radiation treatment delivery codes, including the codes that describe IMRT and Stereotactic Radiation Therapy delivery services. CMS discusses several issues relating to the valuing of direct PE for these services and proposes the RUC recommended direct PE input for these services. CMS requests comment about the apparent contradiction between the CPT instructions and the RUC recommendation.

2. Equipment Utilization Rate for Linear Accelerators
CMS reviews the CMS assumptions used for equipment usage in allocating capital equipment costs to calculate PE RVUs and the associated legislation establishing utilization rates. Based on the RUC assumption that the same type of linear accelerator is now typically used to furnish all levels and types of external beam radiation, because the machines previously used to furnish these services are no longer manufactured, CMS is concerned that they should not continue to assume the equipment is only used for 25 out of a possible 50 hours per week. Based on analysis of Medicare claims data, CMS estimates that under the new code set a single kind of linear accelerator would be used for all of the 65 million minutes furnished to Medicare beneficiaries, a 45 percent increase in the aggregate amount of time the equipment is in use. CMS proposes to adjust the equipment utilization rate assumption for the linear accelerator from 50 percent to 70 percent.

For advanced diagnostic imaging services, CMS’ policy is to change the equipment utilization assumption only by 10 percent per year. Because capital equipment costs are amortized overall several years, CMS thinks it is reasonable to transition changes for particular items over several years. CMS discusses the reasons they believe that the transition to the linear accelerator has already occurred, including the fact the specialty societies recommendations for the new CPT codes were developed in 2013. Instead of a 7-year transition, CMS is proposing a 2-year transition to the 70 percent utilization rate assumption. Specifically, CMS is proposing for PE RVUs to use a 60 percent utilization rate assumption for 2016 and a 70 percent utilization rate assumption for 2017. (The values in addendum B were calculated using the proposed 60 percent utilization rate).

CMS continues to seek empirical data on the capital equipment costs, including equipment utilization rates, for the linac and other capital-intensive machines, and also comments on how to most accurately address issues surrounding those costs within the PE methodology.

3. Superficial Radiation Treatment Delivery
In the 2015 final rule, CMS noted that although changes to the prefatory language for CPT code 77401 bundled services that were previously separately billed into the code, the RUC did not review the inputs for superficial radiation therapy procedures. CMS requested information on whether the new radiation therapy code set combined with the modifications in the prefatory text allowed for appropriate reporting and payment of the services associated with superficial radiation.
CMS received a recommendation to make adjustments to both the physician work and PE components for 77401. In response, CMS is requesting recommendations from the RUC and other stakeholders, regarding whether or not physician work should be added and minutes for the radiation therapists should be removed. They also seek information on the possible inclusion of nurse time for this service.

In response to submitted invoices for the related capital equipment, CMS is proposing to update the equipment item ER045 “orthovoltage radiotherapy system” by renaming it “SRT-100 superficial radiation therapy system” and proposes to update the price from $140,000 to $216,000.

c. Advance Care Planning (ACP)
For 2015, CPT created two new codes describing ACP services:
- CPT code 99497, ACP including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family members and/or surrogate, and
- CPT code 99498, ACP; each additional 30 minutes (List separately in addition to the code for the primary procedure).

For 2015, Medicare does not recognize these codes for reporting and payment for these services. In the 2015 final rule, these codes were assigned a status indicator of “I” (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services) and CMS requested comments about whether they should make separate payment for ACP services.

In response to comments, CMS is proposing to recognize these CPT codes and provide separate payment for CPT codes 99497 and 99498. (Assign status indicator “A”, Active code.) CMS is also proposing to adopt the RUC-recommended values for these codes.

CMS notes that, as with all other Medicare services, the ACP services should be reported when the “described service is reasonable and necessary for the diagnosis or treatment of illness or injury” (Section 1862(a)(1)(A) of the Act). CMS reminds the reader that the presence of an “A” indicator does not mean that there is a national coverage determination for this service and that the Medicare Administrative Contractors are responsible for local coverage decisions in the absence of a national Medicare policy. CMS also indicates that an ACP service could be billed with or without a standard E/M service.

CMS also seeks comments on whether separate payment is needed for ACP and what types of incentives this proposal creates. In addition, they seek comment on whether payment for ACP is appropriate in other circumstances, such as an optional element at the beneficiary’s discretion at the time of the annual wellness visit (Section 1861(hhh)(2)(G) of the Act).

d. Proposed Valuation of Other Codes for 2016
CMS includes a discussion of proposed work RVUs that either vary from those recommended by the RUC or do not have RUC recommendations. The affected codes are listed below (the numbers correspond to the numbers in the proposed rule). Readers with an interest in any of
these codes should review the relevant portion of the proposed rule for code-specific details, which are beyond the scope of this summary.

1. **Excision of Nail Bed** (CPT code 11750)
2. **Bone Biopsy Excisional** (CPT code 20240)
3. **Endobronchial Ultrasound** (CPT codes 31622, 3160A, 3160B, 31625, 31626, 31628, 31629, 3160C, 31632, and 31633)
4. **Laparoscopic Lymphadenectomy** (CPT codes 38570-38572)
5. **Mediastinoscopy with Biopsy** (CPT code 3940A and 3940B)
6. **Hemorrhoid(s) Injection** (CPT code 46500)
7. **Liver Allotransplantation** (CPT code 47135)
9. **Penile Trauma Repair** (CPT codes 5443A and 5443B)
10. **Intrastromal Corneal Ring Implantation** (CPT code 657XG)
11. **Dilation and Probing of Lacrimal and Nasolacrimal Duct** (CPT codes 66801, 68810, 68811, 68815 and 68816)
12. **Spinal Instability Radiologic Examinations** (CPT codes 7208A, 7208B, 7208C, and 7208D)
13. **Echo Guidance for Ova Aspiration** (CPT code 76948)
14. **Immunohistochemistry** (CPT codes 88341, 88342, and 88344)
15. **Immunofluorescent Studies** (CPT codes 88346 and 8835X)
16. **Morphometric Analysis** (CPT codes 88364-69, 88373, 88374, and 88377)
17. **Vestibular Caloric Irrigation** (CPT codes 9254A and 9254B)
18. **Instrument-Based Ocular Screening** (CPT codes 99174 and 9917X)
19. **Low-dose computer tomography, lung, screening (GXXX1) and lung cancer screening counseling and shared decision making (GXXX2)**

CMS also includes a discussion of proposed direct PE inputs that vary from those recommended by the RUC. CMS is also identifying these codes as potentially misvalued because their direct PE inputs were not reviewed at the same time their work RVUs were reviewed. CMS notes that although they are proposing adjusted PE inputs for these codes based on the RUC recommendations, they anticipate corresponding change to direct PE input once the work RVUs and time are addressed. The affected codes are listed below (the letters correspond to the letters in the proposed rule). Readers with an interest in any of these codes should review the relevant portion of the proposed rule for code-specific details, which are beyond the scope of this summary.

a. **Repair of Nail Bed** (CPT code 11760)
b. **Submucosal Ablation of the Tongue Base** (CPT code 41530)
c. **Cytopathology Fluids, Washings or Brushings** (CPT codes 88104, 88106, and 88108)
d. **Cytopathology Smears, Screening and Interpretation** (CPT codes 88160-88162)
e. **Flow Cytometry, Cytoplasmic Cell Surface** (CPT code 88184 and 88185)
f. **Consultation on Referral Slides and Materials** (CPT codes 88321, 88323, and 88325)
g. **Morphometric Analysis, Tumor Immunohistochemistry** (CPT codes 88360 and 88361)
h. **Nerve Teasing Preparation** (CPT code 88362)
i. Nasopharyngoscopy with Endoscope (CPT code 92511)

j. Needle Electromyography (CPT codes 95863, 95864, 95869, and 95870)

J. Medicare Telehealth Services

CMS received several requests in 2014 to add various services as Medicare telehealth services effective for 2016. **CMS proposes to add the following CPT and HCPCS codes** because they believe these services are sufficiently similar to services currently on the telehealth services list (this is known as qualifying on a category 1 basis):

- Prolonged service codes in the inpatient and observation setting (CPT codes 99356 and 99357), CMS notes that the prolonged service codes can only be billed in conjunction with E/M codes on the list of Medicare telehealth services. Thus, these codes can only be billed with subsequent hospital visit every three days via telehealth and one subsequent nursing facility visit every thirty days.

- ESRD-related services (CPT codes 90933-90936). Although these services are for home-based dialysis, and a patient’s home is not an authorized originating site for telehealth, CMS recognizes that many components of these services would be furnished from an authorized originating site and therefore, can be furnished via telehealth. An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit Monthly Capitation Payment code and the 4 or more visit Monthly Capitation Payment code. CMS notes that the required clinical examination of the catheter access site must be furnished face-to-face “hands on” (without the use of an interactive telecommunications system) by a physician, certified nurse specialist, nurse practitioner, or physician’s assistant.

CMS is not proposing to add the following services for the reasons noted:

- All E/M services, telerehabilitation services and palliative care, pain management and patient navigation services for cancer patients. No information on the specific codes requested for telehealth coverage or evidence of clinical benefits was submitted.

- Critical care (CPT codes 99291 and 99292), CMS reviewed the studies submitted by the American Telemedicine Association and determined there was no evidence that the implementation of ICU telemedicine demonstrates a clinical benefit to Medicare beneficiaries. The studies did not demonstrate a significantly reduced mortality rates or hospital length of stay.

- Prolonged E/M service before and/or after direct patient care (CPT codes 99358 and 99359). These codes are not separately payable by Medicare and not considered as a telehealth service.

- Online E/M service (CPT code 99444). This code is a noncovered Medicare service and CMS is not proposing to consider this as a telehealth service.

- Chronic care management (CPT code 99490). CMS notes this service can be furnished without the beneficiary’s face-to-face presence and is not appropriate for consideration as a Medicare telehealth service.

- Medication therapy management provided by a pharmacist (CPT codes 99605-99607). These codes are noncovered Medicare services and CMS is not proposing to add them to the list of telehealth services.
CMS solicits requests to add services to the list of Medicare telehealth services. To be considered for the 2017 rulemaking, requests must be received by December 31, 2015. Information about submitting a request is on the CMS website at: [www.cms.gov/telehealth/](http://www.cms.gov/telehealth/).

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

**Proposal to Amend §410.78 to Include Certified Registered Nurse Anesthetists (CRNA) as Practitioners for Telehealth Services**

Under section 1834(m)(l) of the Act, Medicare makes payment for telehealth services furnished by physicians and practitioners; for telehealth practitioner includes a CRNA as defined in section 1861(bb)(2). CMS notes that in the regulations they omitted CRNAs from the list of distant site practitioners for telehealth services because they did not believe CRNAs would furnish any of the services on the list of Medicare telehealth services. CRNAs are licensed in some states to furnish some of the services on the telehealth list, including E/M services, and CMS is proposing to revise the regulations at §410.78(b)(2) to include a CRNA.

**K. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements**

CMS proposes to revise the “incident to” regulations under §410.26 and related sections of the regulations that set forth the requirements for which physicians or other practitioners (collectively in this section referred to as “physicians”) can bill for incident to services.

** Billing Physician as Supervising Physician.** To be certain that the incident to services furnished to a beneficiary are in fact an integral, although incidental, part of the physician’s personal professional service that is billed to Medicare, CMS clarifies that the physician who bills for the incident to service must also be the physician who furnishes the service or who directly supervises the service. CMS believes this is consistent with the requirements that all physicians attest on each Medicare claim that he or she “personally furnished” the services for which he or she is billing. Thus, CMS proposes to remove the last sentence from §410.26(b)(5), which specifies that the physician supervising the auxiliary personnel does not need to be the same physician upon whose professional service the incident to service is based.

**Auxiliary Personnel Who Have Been Excluded or Revoked from Medicare.** As a condition of Medicare payment, auxiliary personnel who, under the direct supervision of a physician, provide incident to services to Medicare beneficiaries must comply with all applicable federal and state laws, including not having been excluded by the OIG from Medicare, Medicaid and all other federally funded health care programs. CMS proposes to explicitly prohibit auxiliary personnel from providing incident to services who have either been excluded from Medicare, Medicaid and all other federally funded health care programs by the OIG or who have had their enrollment revoked for any reason.

CMS notes that these proposed revisions to the incident to regulations will provide the program with additional recourse for denying or recovering Part B payment for incident to services and
supplies that are not furnished in compliance with program requirements. **CMS invites comments** about possible approaches the agency could take to ensure that incident to services are provided to beneficiaries by qualified individuals in a manner consistent with Medicare statute and regulations, including creating new categories of enrollment; implementing a mechanism for registration short of full enrollment; requiring the use of claim elements such as modifiers to identify the types of individuals providing services; or relying on post-payment audits, investigations and recoupments by CMS contractors, such as RACs or Program Integrity Contractors.

**L. Portable X-ray: Billing of the Transportation Fee**

Portable X-ray suppliers receive a transportation fee for transporting portable X-ray equipment to the location where the portable X-rays are taken and the portable X-ray transportation fee is allocated among the patients. CMS received feedback that there have been different interpretations about how the transportation payment is prorated among patients.

CMS is proposing to revise the Medicare Claims Processing Manual (Pub. 100-4, Chapter 13, Section 90.3) to remove the word “Medicare” before “patient” in section 90.3 (The sentence currently reads, “When more than one Medicare patient is X-rayed at the same location, e.g. a nursing home. Prorate the single fee schedule transportation payment among all patients receiving the services.) **CMS is also proposing to clarify that this guidance means that when more than one patient is X-rayed at the same location, the single transportation payment under the PFS is to be prorated among all patients (Medicare Parts A and B, and non-Medicare) receiving portable A-ray services during that trip, regardless of insurance status.**

**M. Technical Corrections – Waiver of Deductible for Anesthesia Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test**

In the 2015 final rule, CMS stated that the statutory waiver of the deductible would apply to anesthesia services furnished in conjunction with a colorectal cancer screening test even when a polyp or other tissue is removed during the colonoscopy. CMS did not amend the regulations to reflect this policy and is proposing a technical correction to amend §410.160(b)(8) to make a conforming change to reflect the inapplicability of the deductible to these anesthesia services.

**III. Other Provisions of the Proposed Regulations**

**A. Proposed Provisions Associated with the Ambulance Fee Schedule**

1. **Ambulance Extender Provisions**

In light of Congressional actions taken in MACRA, CMS extends the following special ambulance payment policies through December 31, 2017:  
- 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.

2. Proposed Changes in Geographic Area Delineations for Ambulance Payment

CMS proposes to continue implementation of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13-01 for 2016 and subsequent years to more accurately identify urban and rural areas for ambulance fee schedule payment purposes.

In addition, CMS proposes to continue to use 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. Consistent with this policy, CMS proposes for 2016 and subsequent years to designate as rural areas those census tracts that fall at or above RUCA level 4.0. CMS would not designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people, as CMS has determined it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level.

CMS says that adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. However, under the proposed rule, CMS notes that of the 42,925 ZIP codes in the U.S. approximately 95 percent are unchanged by OMB’s revised delineations and the updated RUCA codes, 4 percent of ZIP codes would change from rural to urban and 1 percent of ZIP codes would change from urban to rural, meaning that ambulance providers and suppliers in those areas may experience payment decreases or increases, respectively. CMS notes that West Virginia would have the most ZIP codes changing from rural to urban, while Ohio would have the most ZIP codes changing from urban to rural. Table 16 provides a state-by-state assessment of the impact of the revised OMB delineations and updated RUCA codes. CMS notes that it is not proposing a delay in implementation or a transition period for the revised OMB delineations and updated RUCA codes for 2016 and subsequent years.

**CMS invites public comments on its proposals to continue implementation of the revised OMB delineations as set forth in OMB’s February 28, 2013 bulletin (No. 13-01) and the most recent modifications of the RUCA codes 2016 and subsequent years for purposes of payment under the ambulance fee schedule. In addition, CMS invites public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes.**
CMS estimates that its continued implementation of these geographic delineations would have minimal fiscal impact because it is a continuation of the same revised OMB delineations and updated RUCA codes that were in effect in 2015.

3. Proposed Changes to the Ambulance Staffing Requirement

Under current regulations, Section 410.41(b)(1), CMS requires that a vehicle furnishing ambulance services at the Basic Life Support (BLS) level must be staffed by at least two people, one of whom must meet the following requirements: (1) be certified as an emergency medical technician by the state or local authority where the services are furnished, and (2) be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. In a July 2015 report by the OIG (13-0006) entitled “Medicare Requirements for Ambulance Crew Certification,” the OIG found that a second crew member: (1) possessed a lower level of training than required by state law, or (2) had purchased or falsified documentation to establish their credentials. CMS proposes to revise §410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished, and the current Medicare requirements under §410.41(b). CMS believes that this would, in effect, require both of the required ambulance vehicle staff to also satisfy any applicable state and local requirements that may be more stringent than those currently set forth at §410.41(b), consistent with OIG’s recommendation.

In addition, CMS proposes to revise §410.41(b) and the definition of Basic Life Support (BLS) in §414.605 to clarify that, for BLS vehicles, at least one of the staff members must be certified at a minimum as an emergency medical technician–basic (EMT-Basic), which it believes would more clearly state its current policy. Finally, CMS proposes to revise the definition of Basic Life Support (BLS) in §414.605 to delete the last sentence, which sets forth examples of certain state law provisions, as CMS is concerned that this sentence may not accurately reflect the status of the relevant state laws over time.

CMS invites public comments on its proposals to revise the ambulance vehicle staffing requirements in §410.41(b) and §414.605 as discussed above.

B. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

A RHC or FQHC visit must be a face-to-face encounter between the patient and a RHC or FQHC practitioner (physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker, and under certain conditions, an RN or LPN furnishing care to homebound RHC or FQHC patients) during which time one or more RHC or FQHC services are furnished. A transitional care service can also be a RHC or FQHC visit.

RHCs are paid an all-inclusive rate for medically necessary medical and mental health services, and most qualified preventive health services furnished on the same day. FQHCs are transitioning to a FQHC PPS system in which they are paid based on the lesser of a national
encounter-based rate or their total adjusted charges. RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services.

**CMS is proposing to establish, beginning on January 1, 2016, additional payments for RHCs and FQHCs for the costs of CCM services that are not already captured in the RHC or FQHS payments.** CMS notes that this proposal is based, in large part, on the overwhelming supportive comments they received about CCM services in response to the May 2, 2014 final rule about RHC and FQHC payments (79 FR 25447).

**Proposed Payment Methodology and Billing for CCM Services**

CMS notes the requirements they are proposing for RHCs and FQHCs to receive payment for CCM services are consistent with those finalized in the 2015 PFS final rule and are summarized in Table 17 of this proposed rule. CMS proposes to establish payment for RHC and FQHCs who furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Only one practitioner can bill this code per month. CMS proposes that a RHC or FQHC can bill for CCM services furnished by, or incident to a RHC or FQHC physician, nurse practitioner, physician assistant or certified nurse midwife. The proposed rule discusses additional components of CCM services that are specific to RHCs and FQHCs. CMS states that additional information will be provided in subregulatory guidance.

CMS is proposing that payment for CCM be based on the PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim. For the first quarter of 2015, the national average payment rate is $42.91 per beneficiary per calendar month. CMS proposes to waive the RHC and FQHC face-to-face requirements when CCM services are furnished. Coinsurance would be applied as applicable to FQHC claims, and coinsurance and deductibles would apply as applicable to RHC claims. CMS plans to provide detailed billing instructions in subregulatory guidance. In the proposed rule, CMS discusses other options they considered for adding CCM services and the reasons why they did not propose any of these alternatives.

**Proposed Beneficiary Eligibility Requirements**

Under the PFS, beneficiary notification and consent is required before a provider can furnish and bill for CCM services. CMS proposes consistent requirements before the RHC or FQHC can furnish or bill for CCM services. These requirements include:

- The eligible beneficiary must be informed about the availability of CCM services, how they differ how any care management services currently provided, and the applicability of coinsurance.
- The eligible beneficiary must provide their written agreement to have the services provided, including electronic communication of patient information with other treating providers as part of care coordination.
- The RHC or FQHC must document in the medical record the patient’s decision.

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• The eligible beneficiary must be informed that CCM services could be revoked by the beneficiary at any time either verbally or in writing.
• A copy of the care plan must be given to the beneficiary and be maintained in the electronic medical record.

Impact Analysis
CMS estimates that the 10-year cost impact of CCM payments in RHCs and FQHCs would be $1.970 billion, of which $480 million is the premium offset and $1.490 billion is the Part B payment (Table 47).

C. Healthcare Common Procedure Coding System (HCPCS) Coding for RHCs

As a result of the HIPAA amendments, HHS adopted regulations pertaining to data standards for health care related transactions. These regulations require a covered entity (defined to include a provider of medical or health services) and define the types of standard transactions. According to the regulations, a covered entity must use the applicable code sets that are valid at the time the health care is furnished; the standard medical data code sets adopted by the Secretary are HCPCS codes.

CMS notes that RHCs are considered covered entities. Effective for dates of services on or after January 1, 2016, CMS is proposing to require HCPCS coding for all services furnished by RHCs to Medicare beneficiaries. Under this proposal a HCPCS code would be reported along the required Medicare revenue code for each service furnished by the RHC to a Medicare patient. There would not be any change in the payment methodology for RHCs. As part of the implementation of the HCPCS coding requirement, CMS plans to provide additional information through program instructions. CMS invites RHCs to submit comments on the feasibility of updating their billing systems to meet the January 1, 2016 implementation.

D. Payment to Grandfathered Tribal FQHCs that were Provider-Based Clinics on or Before April 7, 2000

CMS is proposing that clinics that were provider-based to an Indian Health Service (IHS) hospital on or before April 7, 2000 and are now tribally operated clinics contracted or compacted under the Indian Self Determination Education Assistance Act, may seek to become certified as grandfathers tribal FQHCs. CMS also proposes that these grandfathered tribal FQHCs retain their Medicare outpatient per visit payment rate, as set annually by the IHS, rather than the FQHC PPS per visit base rate of $158.85. Additional discussion is provided in the proposed rule.

E. Part B Drugs

Payment for Biosimilar Biological Products Under Section 1847A

Section 3139 of the ACA amended section 1847 of the Act to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar
biological products using the average sale price (ASP) methodology. A biosimilar biological product is defined as a biological product approved under an abbreviated application for a license that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). A reference biological product for a biosimilar product is defined as the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

In the 2011 PFS final rule CMS finalized policies to implement these provisions (75 FR 73393 and 77394), the relevant regulation text is at §414.902 and §414.904. CMS notes there is a potential inconsistency between CMS’ interpretation of the statutory language at section 1847(b)(8) of the Act and the regulation text at §414.904(j). CMS proposes to clarify existing regulation text to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included with the same billing and payment code. CMS also proposes to update the effective date of this provision from July 1, 2010 to January 1, 2016.

Clarification of the Part B Biosimilar Payment Policy

CMS plans to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. Thus products that rely on a common reference product’s biological license application will be grouped into the same payment calculation. CMS notes this approach is similar to the ASP calculation for multiple source drugs.

CMS describes how payment for newly approved biosimilar will be determined. As discussed in the 2011 PFS final rule, CMS anticipates that as subsequent biosimilar biological products are approved, they will receive manufacturers’ ASP sales data through the ASP data submission process and publish national payments amount, consistent with the approach to other drugs and biological that are paid under section 1847A of the Act. Until CMS has collected sufficient sales data as reported by the manufacturers, payment limits will be determined in accordance with the provisions in section 1847A(c)(4) of the Act. If no manufacturer data is collected, prices will be determined by local contractors using any available pricing information, including provider invoices. Once a biosimilar is approved by the FDA, Medicare B payment would be available and payment may be made before a HCPCS code is provided, provided the claim is reasonable and necessary and meets applicable coverage criteria.

CMS also clarifies how wholesale acquisition cost (WAC) data may be used for Medicare payment of biosimilars. Section 1847A(c)(4) of the Act authorizes the use of a WAC-based payment amount when the ASP during the first quarter of sales is not sufficiently available from the manufacturer to compute an ASP-based payment amount. Once the WAC data is available from the pharmaceutical pricing compendia and when WAC-based payment amounts are used to determine the national payment limit for a biosimilar product, the payment limit will be 106 percent of the WAC of the biosimilar product. The reference biological product is not factored into the WAC-based payment limit determination. Once ASP information is available for the biosimilar product, and when partial quarterly pricing requirements no longer apply, the Medicare payment limit for a biosimilar product will be determined based on ASP data.
F. Productivity Adjustment for the Ambulance, Clinical Laboratory, and DMEPOS Fee Schedules

Section 3401 of the Affordable Care Act requires that in 2011 (and in subsequent years) update factors under the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS) and the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule be adjusted by changes in economy-wide productivity. Beginning with 2016, for the AFS, CLFS and DMEPOS fee schedule, the multifactor productivity (MFP) adjustment is calculated using a revised series developed by IHS Global Insight, Inc. (IGI) to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of Bureau of Labor Statistics (BLS) aggregate capital inputs recently developed by IGI using a regression model. CMS states that this series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. CMS is using IGI’s most recent forecast of the BLS capital inputs series in the MFP calculations beginning with 2016. A complete description of the MFP projection methodology is available on the CMS website at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html

G. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

1. Background, Statutory Authority and Requirements

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The proposed rule outlines the initial component of the new Medicare AUC program and the CMS plan for implementing the remaining components.

As way of background, AUC are a set of individual criteria that presents information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. CMS notes its previous experience in the Medicare Imaging Demonstration and consideration of others’ experiences and results from implementation at healthcare organizations such as Brigham & Women’s, Intermountain Healthcare, Kaiser, Massachusetts General Hospital, and Mayo, and in states such as Minnesota. CMS notes its belief that a successful AUC program would allow flexibility, and under section 1834(q) of the Act, it foresees competing sets of AUC developed by different provider entities, and competing clinical decision support (CDS) mechanisms, from which providers may choose.

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). In the proposed rule, CMS primarily address the first component under section 1834(q)(2) – the
process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1).

With respect to the relevant definitions under section 1834(q)(1), this section provides definitions of terms for AUC, applicable imaging service, applicable setting, ordering professional, and furnishing professional. CMS provides clarification on some of the definitions provided in this section in its proposal for implementation (discussed below). CMS notes that an “applicable imaging service” must be an advanced imaging service as defined in section 1834(e)(1)(B) of the Act, which defines “advanced diagnostic imaging services” to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services CMS may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services.

With respect to the first component, establishment of AUC by November 15, 2015 (section 1834(q)(2)), CMS discussed the statutory requirements within this provision that CMS plans to address in its proposals:

- Section 1834(q)(2)(A) of the Act requires the Secretary to specify applicable AUC for applicable imaging services, through rulemaking and in consultation with physicians, practitioners and other stakeholders, by November 15, 2015.
- Section 1834(q)(2)(B) of the Act identifies certain considerations the Secretary must take into account when specifying applicable AUC including whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders.
- Section 1834(q)(2)(C) of the Act requires the Secretary to review the specified applicable AUC each year to determine whether there is a need to update or revise them, and to make any needed updates or revisions through rulemaking.
- Section 1834(q)(2)(D) of the Act specifies that, if the Secretary determines that more than one AUC applies for an applicable imaging service, the Secretary shall apply one or more AUC for the service.

CMS notes that the new Medicare AUC program was not part of last year’s 2015 proposed rule because CMS had less than one month to develop a proposal for the PFS rulemaking process (provisions were part of PAMA that was enacted into law on April 1, 2014). CMS also notes it has met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program.

The second major component of the Medicare AUC program is the identification of qualified clinical decision support (CDS) mechanisms that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. CMS envisions a CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user and that is ideally integrated directly into, or be seamlessly interoperable with, existing health information technology (IT) systems. CMS notes that it is not including proposals to implement this section of the Act as it first needs to establish, through notice and comment rulemaking, the process for specifying applicable AUC. CMS anticipates that in PFS
rulemaking for 2017, it will provide clarifications, develop definitions and establish the process by which it will specify qualified CDS mechanisms.

The third major component of the AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a listed qualified CDS mechanism when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional’s consultation with a qualified CDS mechanism. Again, CMS is not including proposals to implement section 1834(q)(4) of the Act in this proposed rule, as it first wants to first establish through notice and comment rulemaking the process by which applicable AUC will be specified as well as the CDS mechanisms through which ordering providers would access them. CMS anticipate including further discussion and adopting policies regarding claims-based reporting requirements in the 2017 and 2018 rulemaking cycles.

The fourth component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. This section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. CMS is not including proposals to implement these sections in this proposed rule, but does offer proposals (discussed below) to identify outlier ordering professionals from within priority clinical areas that would be established through subsequent rulemaking, and a process to provide clarity around priority clinical areas.

2. Proposals for Implementation

CMS proposes to amend its regulations to add a new §414.94, “Appropriate Use Criteria for Certain Imaging Services.”

CMS invites public comment on its proposals (described below), and is particularly interested in comments on the proposed definition of provider-led entity as these are the organizations that have the opportunity to become qualified to develop, modify, or endorse specified AUC.

a. Definitions

In §414.94 (b), CMS proposes to codify and add language to clarify some of the definitions provided in section 1834(q)(1) of the Act as well as define terms that were not defined in statute but for which CMS believes a definition would be helpful for program implementation. CMS notes that due to circumstances unique to imaging, there is an ordering professional (the physician or practitioner that orders that the imaging service be performed) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the radiologic interpretation of the image) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.
This proposed AUC program only applies in applicable settings: a physician’s office, a hospital outpatient department (including an emergency department) and an ambulatory surgical center. The inpatient hospital setting is not an applicable setting.

CMS proposes to clarify the definition for appropriate use criteria, which is defined in statute to include only criteria developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based. CMS proposes to add the following language to this definition: AUC are a collection of individual appropriate use criteria. Individual criteria are information presented in a manner that links: a specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s).

For the purposes of implementing this program, CMS proposes to define new terms in §414.94(b). A provider-led entity would include national professional medical specialty societies (for example the American College of Radiology and the American Academy of Family Physicians) or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare (for example hospitals and health systems). CMS notes that applicable AUC become specified when they are developed, modified or endorsed by a qualified provider led entity.

b. AUC Development by Provider-Led Entities
In §414.94, CMS proposes to include regulations to implement the first component of the Medicare AUC program—specification of applicable AUC. To meet the statutory requirements in section 1834(q)(2)(B), CMS proposes that AUC developed, modified, or endorsed by qualified provider-led entities will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

In order to become and remain a qualified provider-led entity, CMS proposes to require a provider-led entity to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. These requirements are summarized in the table below.

<table>
<thead>
<tr>
<th>Proposed requirement to become and remain a provider-led entity</th>
<th>Description of what is required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entities must engage in a systematic literature review of the clinical topic and relevant imaging studies</td>
<td>Literature review to include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. Evidence must be assessed using a formal, published, and widely recognized methodology for grading evidence. Evidence assessment must include relevant published evidence-based guidelines and consensus statements by</td>
</tr>
</tbody>
</table>
professional medical specialty societies.

Published consensus statements may form part of the evidence base of AUC and would be subject to the same evidentiary grading methodology.

<table>
<thead>
<tr>
<th>Provider-led entity’s AUC development process must be led by at least one multidisciplinary team with autonomous governance that is accountable for developing, modifying, or endorsing AUC.</th>
<th>At a minimum, the team must be composed of three members: one with expertise in the clinical topic related to the criterion and one with expertise in imaging studies related to the criterion. CMS encourages (does not propose requiring) the team to be larger, and include experts in each of the following domains: statistical analysis (such as biostatics, epidemiology, and applied mathematics); clinical trial design; medical informatics; and quality improvement. CMS notes that a given team member may be the team’s expert in more than one domain and must be substantial contributor, not just a reviewer.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider-led entity must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team</td>
<td>Must disclose any direct or indirect relationships, as well as ownership or investment interests, among the multidisciplinary team members or immediate family members and organizations that may financially benefit from the AUC that are being considered for development, modification or endorsement.</td>
</tr>
<tr>
<td>Public transparency requirements:</td>
<td>Proposes that the provider-led entity must maintain on its website each criterion that is part of the AUC that the entity has considered or is considering for development, modification, or endorsement. Proposes that key decision points in individual criteria should be graded in terms of strength of evidence using a formal, published, and widely recognized methodology. Detail should be part of the entity’s website. Proposes that provider-led entity’s process for developing, modifying, or endorsing AUC (which would be inclusive of the requirements being proposed in this rule) must be publicly posted on the entity’s website.</td>
</tr>
</tbody>
</table>

**c. Process for Provider-Led Entities to Become Qualified to Develop, Endorse or Modify AUC**

CMS proposes that provider-led entities must apply to CMS to become qualified. CMS proposes that the application (not a CMS form and must be created by the applicant entry) must include a statement as to how the entity meets the definition of a provider-led entity and how the entity would adhere to each of the qualification requirements. Applications will be accepted by CMS.
each year, but must be received by January 1. CMS will publish a list of applicants it determines to be qualified provider-led entities by the following June 30 at which time all AUC developed or endorsed by that provider-led entity will be considered to be specified AUC. All qualified provider-led entities must re-apply every 6 years and their applications must be received by January 1 during the 5th year of their approval.

d. Identifying Priority Clinical Areas
CMS proposes to identify priority clinical areas of AUC that it will use in identifying outlier ordering professionals. CMS notes that while there is no consequence to being identified as an outlier ordering professional until January 2020, it is important to allow ordering and furnishing professionals as much time as possible to use and familiarize themselves with the specified applicable AUC that will eventually become the basis for identifying outlier ordering professionals.

To identify these priority clinical areas, CMS states that it may consider a number of factors: incidence and prevalence of diseases, as well as the volume, variability of utilization, strength of evidence for imaging services, and the applicability of the clinical area to a variety of care settings, and to the Medicare population. CMS proposes to annually solicit public comment and finalize clinical priority areas through the PFS rulemaking process beginning in 2017. To further assist, CMS proposes to convene the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), as needed, to examine the evidence surrounding certain clinical areas. CMS notes that future rulemaking will address further details.

e. Identification of Non-Evidence Based AUC
CMS remains concerned that non-evidence based criteria may be developed or endorsed by qualified provider-led entities, and thus proposes a process by which it would identify and review potentially non-evidence-based criteria that fall within one of the identified priority clinical areas. CMS proposes to accept public comment in identifying AUC that potentially are not evidence-based through annual PFS rulemaking and foresees this being a standing request in all future rules. CMS also proposes to use the MEDCAC to further review the evidentiary basis of these identified AUC, as needed, given their extensive experience in reviewing, interpreting, and translating evidence.

3. Information Collection Requirements Regarding AUC Criteria

CMS estimates a one-time burden associated with organizations interested in preparing and submitting an application to be recognized as a qualified provider-led entity. CMS anticipates 30 organizations to apply. In aggregate, CMS estimates 900 hrs (30 hrs x 30 submissions) at $83,502 ($2,783.40 x 30 submissions). Qualified provider-led entities must re-apply every 6 years. CMS expects the ongoing burden for re-applying to be half the burden of the initial application process.
H. Physician Compare Website

1. Background

Previously finalized policies for public reporting on Physician Compare are reviewed in the proposed rule and summarized in Table 18, which is reproduced immediately below. The discussion includes a review of CMS policies regarding validity and reliability of data for public reporting (regarding which CMS refers readers to the 2015 final rule (70 FR 67764-67765)), the minimum sample size of 20 patients, and the inclusion of only those measures deemed statistically comparable (i.e., those proven to measure the same phenomena in the same way regardless of the mechanism through which they were collected.)

<table>
<thead>
<tr>
<th>Data Collection Year</th>
<th>Publication Year</th>
<th>Reporting Mechanism</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 Incentive Program, and participants in the EHR Incentive Program.</td>
</tr>
<tr>
<td>2012</td>
<td>February 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 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 Incentive Program, 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>2013</td>
<td>December 2014</td>
<td>WI</td>
<td>3 DM and 1 CAD measures collected via the WI for groups of 25 or more EPs with a minimum sample size of 20 patients.</td>
</tr>
<tr>
<td>2013</td>
<td>December 2014</td>
<td>Survey Vendor</td>
<td>6 CAHPS for ACO summary survey measures for Shared Savings Program ACOs.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected 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 late 2015</td>
<td>WI, EHR, Registry</td>
<td>All measures reported via the WI, 13 EHR, and 16 registry measures for group practices of 2 or more EPs reporting under PQRS with a minimum sample size of</td>
</tr>
<tr>
<td>Data Collection Year</td>
<td>Publication Year</td>
<td>Reporting Mechanism</td>
<td>Quality Measures and Data for Public Reporting</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------</td>
<td>---------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>2014</td>
<td>Expected late 2015</td>
<td>WI, Survey Vendor Administrative Claims</td>
<td>20 patients. Include composites for DM and CAD, if available.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected late 2015</td>
<td>WI, Certified Survey Vendor</td>
<td>All measures reported by Shared Savings Program ACOs, including CAHPS for ACO and claims based measures.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected late 2015</td>
<td>Registry, EHR, or Claims</td>
<td>Up to 12 CAHPS for PQRS 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.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected late 2015</td>
<td>Registry</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 registry, EHR, or claims with a minimum sample size of 20 patients.</td>
</tr>
<tr>
<td>2014</td>
<td>Expected late 2015</td>
<td>Registry</td>
<td>Measures from the Cardiovascular Prevention measures group reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>WI, EHR, Registry, Claims</td>
<td>Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include indicator for EPs who report 4 individual PQRS measures in support of Million Hearts.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>WI, EHR, Registry</td>
<td>All PQRS measures for group practices of 2 or more EPs.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>WI, Survey Vendor Administrative Claims</td>
<td>All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs and claims based measures.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>Certified Survey Vendor</td>
<td>All CAHPS for PQRS measures reported for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>Registry, EHR, or Claims</td>
<td>All PQRS measures for individual EPs collected through a registry, EHR, or claims.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>Registry, EHR, or Claims</td>
<td>4 PQRS measures reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.</td>
</tr>
<tr>
<td>2015</td>
<td>Expected late 2016</td>
<td>QCDR</td>
<td>All individual EP QCDR measures, including PQRS and non-PQRS measures.</td>
</tr>
</tbody>
</table>

2. Data Elements for Physician Compare
CMS proposes to continue to expand the information included on Physician Compare and in the accompanying downloadable database. With one exception, noted in the discussion below, the specific proposals are for publication in 2017 (data collection year 2016). The proposals are discussed here and reflected in proposed rule Table 19, which is reproduced at the end of this section of the summary.

**Benchmarking and Star Ratings.** In order to provide consumers with a point of comparison for the information published on Physician Compare, CMS previously proposed, but did not finalize, application of the Shared Savings Program ACO benchmarking methodology to Physician Compare. In this rule, CMS proposes a different benchmarking methodology. Specifically, CMS proposes to adopt the Achievable Benchmark of Care (ABC™) methodology, which CMS says is a “well-tested, data-driven methodology.” In addition, CMS proposes to use the benchmark to “systematically assign stars for the Physician Compare 5-star rating”. (Currently for some group practice and ACO measures, Physician Compare uses stars as a graphical representation of performance on a measure, with each star representing 20 percent, displayed along with the actual percentage score.²) The proposed rule does not address how CMS intends to use the proposed benchmark to assign star ratings.

Under the ABC™ methodology, a benchmark for a measure or item is calculated as the performance score among the subset of top performers (EPs or groups, as appropriate for the measure) that account for 10 percent of the patient population. The performance score would equal the total number of patients among the top performers receiving the intervention/desired level of care/desired outcome assessed under the measure divided by the total number of all patients measured by these top performers. The methodology includes adjustments to account for low denominators and CMS notes that it is designed to account for all the data collected for a quality measure in the benchmark. The proposed rule includes a detailed example of how the calculation works, and cites a number of journal articles regarding the ABC™ methodology.

**Value Modifier.** The eligible professional (EP)³ and group practice profile pages on Physician Compare indicating Medicare quality program participation with a green check mark would include the names of individual EPs and group practices who received an upward adjustment from the Value-based payment Modifier (VM). This information would be updated annually. The 2018 VM would be based on 2016 data and included on the site no earlier than late 2017. CMS believes that this information would help consumers identify higher quality care provided at lower cost and that the use of a check mark is a user-friendly way to display a complicated concept.

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³ For purposes of participating in PQRS, the term “eligible professional” (EP) means a physician; physician assistant; nurse practitioner; clinical nurse specialist; certified registered nurse anesthetist (an anesthesiologist assistant); certified nurse-midwife; clinical social worker; clinical psychologist; registered dietitian or nutrition professional; audiologist; physical therapist; occupational therapist; qualified speech-language pathologist. [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_List_of_Eligible_Professionals.pdf](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_List_of_Eligible_Professionals.pdf).
Million Hearts. Physician Compare includes an indicator for individual EPs who choose to report on measures that support the HHS “Million Hearts” initiative. The specific measures have changed from year to year. CMS proposes in this rule that the indicator annually reflect whether the EP satisfactorily reported the cardiovascular prevention measures group being proposed under PQRS in this rule. (See section III.I.5 below.)

PQRS and ACO Reporting. CMS proposes to continue to make available annually on Physician Compare all PQRS Group Practice Reporting Option measure performance rates across all reporting mechanisms for groups of 2 or more EPs; performance rates for all measures reported by Shared Savings Program ACOs, including the Consumer Assessment of Healthcare Providers and Systems patient survey; and PQRS measure performance rates across all EP reporting mechanisms.

Individual EP and Group Practice QCDR Measure Reporting. CMS previously provided for public reporting of individual EP level Qualified Clinical Data Registry (QCDR) measures available for public reporting beginning with 2015 data. This includes both PQRS and non-PQRS measure data. CMS proposes to continue to make available for public reporting all individual EP level QCDR measure data that have been collected for at least a full year. In addition, this would be expanded to include QCDR measure performance data for group practices as well. In this case a group practice would be 2 or more EPs billing under the same Tax Identification Number. The QCDR would be required to declare during its self-nomination whether it plans to either post data on its own website and allow Physician Compare to link to it or provide data to CMS for public reporting on Physician Compare. This decision would be final for the reporting year. If no declaration is made, the data would be considered available for reporting on Physician Compare.

Patient Experience of Care Measures. CMS proposes to continue to make available for public reporting all patient experience data for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor. The data are the CAHPS for PQRS measures, which include the Clinical and Group (CG) CAHPS core measures. Specifically, CMS proposes to annually make available the top-box performance rate\textsuperscript{4} for 12 summary survey measures.

Board Certification. Currently, the individual EP profiles on Physician Compare include American Board of Medical Specialties data. CMS proposes to add board certification information from the American Board of Optometry and the American Osteopathic Association. CMS emphasizes that it is not endorsing any particular boards, that these boards showed interest in being added to the website and demonstrated that they have the data to facilitate inclusion of this information on the website. The proposed addition applies only to these two boards; CMS will review interest from other boards that may be brought to its attention.

\textsuperscript{4} Top Box score refers to the most favorable response category for a given measure. For example, if the measure has a scale of “always,” “sometimes,” “never,” the Top Box score is “always”. For the CAHPS for PQRS doctor rating, the Top Box score is a rating of 9 or 10.
3. Additions to the Downloadable Data Base

**VM Information.** CMS also proposes to add information to the Physician Compare downloadable database. This currently includes the quality information reported on Physician Compare and all measures submitted and reviewed and found to be statistically valid and reliable. Under the proposal, the database would also include, for group practices and individual EPs, the 2018 VM quality tiers for cost and quality (2016 data) noting whether the group or EP is high, low, or average on cost and quality. The VM payment adjustment would also be included and an indication of whether the individual or group was eligible to but did not report measures to CMS. CMS intends to conduct consumer testing to ensure that VM data beyond the indicator of upward adjustment proposed above for Physician Compare can be explained in a way that is easily understood by and useful to consumers.

**Utilization information.** Section 104(e) of MACRA requires that beginning with 2016, the Secretary shall integrate Part B utilization information on Physician Compare. CMS proposes that currently available data generated from Part B claims that provide counts of services and procedures rendered by HCPCS code be added to the Physician Compare downloadable database. (These data are available at [http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html).) Because these data are less immediately useable in their raw form by the average Medicare beneficiary, CMS does not propose including this information on the Physician Compare website profile pages.

<table>
<thead>
<tr>
<th>Data Collection Year</th>
<th>Publication Year</th>
<th>Data Type</th>
<th>Reporting Mechanism</th>
<th>Proposed Quality Measures and Data for Public Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>2017</td>
<td>PQRS, PQRS GPRO, EHR, 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 Cardiovascular Prevention measures group proposed under PQRS in support of Million Hearts</td>
</tr>
<tr>
<td>2016</td>
<td>2018</td>
<td>PQRS, PQRS GPRO</td>
<td>Web Interface, EHR, Registry, Claims</td>
<td>Include an indicator for individual EPs and group practices who receive an upward adjustment for the VM.</td>
</tr>
<tr>
<td>2016</td>
<td>2017</td>
<td>PQRS GPRO</td>
<td>Web Interface, EHR, Registry</td>
<td>All 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. Publicly report an item-level benchmark, as appropriate.</td>
</tr>
<tr>
<td>2016</td>
<td>2017</td>
<td>ACO</td>
<td>Web Interface, Survey Vendor Claims</td>
<td>All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs.</td>
</tr>
</tbody>
</table>
### Data Collection Year | Publication Year | Data Type | Reporting Mechanism | Proposed Quality Measures and Data for Public Reporting
--- | --- | --- | --- | ---
2016 | 2017 | CAHPS for PQRS | CMS-Specified Certified CAHPS Vendor | All CAHPS for PQRS measures for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.

2016 | 2017 | PQRS | Registry, EHR, or Claims | All PQRS measures for individual EPs collected through a registry, EHR, or claims. Publicly report an item-level benchmark, as appropriate.

2016 | 2017 | QCDR data | QCDR | All individual EP and group practice QCDR measures.


2016 | 2017 | PQRS, PQRS GPRO | Web Interface, EHR, Registry, Claims | The following data for group practices and individual EPs in the downloadable database:

- The VM quality tiers for cost and quality, noting if the group practice or EP is high, low, or neutral on cost and quality per the VM.
- A notation of the payment adjustment received based on the cost and quality tiers.
- An indication if the individual EP or group practice was eligible to but did not report quality measures to CMS.

### 4. Possible Future Data Elements

CMS seeks comment on several additional data elements for possible future inclusion on the individual EP and group profile pages of Physician Compare. These are:

- **Measures and measure concepts that would fill gaps in those currently available for reporting on Physician Compare and best meet the needs of consumers and other stakeholders.** The measures CMS would consider for future posting on Physician Compare are those that have been comprehensively vetted and tested and are trusted by the physician community.

- **Adding information on the EP and group profile pages about which Medicare Advantage health plans the EP or group accepts.** A link would be provided to information about the plan on the Medicare.gov Plan Finder website. CMS notes that physicians and professionals who participate in Medicare Advantage do not have quality measures available on Physician Compare, and adding a link would ensure that consumers have access to all quality data available in making a health care decision.
• **Inclusion of information on downward and neutral VM adjustments on the individual EP and group practice profile pages.** (As noted above, in this rule CMS proposes to add an upward VM adjustment indicator.) Additionally, comments are sought on whether to include the VM cost composite or other VM cost measure data on the profile pages or in the downloadable data base. CMS notes that these data are an assessment of efficiency, but the complexity means they need time to establish the best method of public reporting to ensure that the information is properly interpreted by consumers.

• **Inclusion of Open Payments data on financial relationships among doctors, hospitals and health care manufacturers on Physician Compare profile pages.** CMS indicates that prior to making a formal proposal to include these data it can continue consumer testing to determine how to best present the information in a way that assists decision making.

• **Stratification of EP and group practice quality measure data by race, ethnicity and gender, if feasible and statistically appropriate.** Comments are also invited on possible Physician Compare quality measures, including composites, that would help consumers and stakeholders monitor trends in health equity.

### I. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

In this section of the proposed rule CMS addresses proposals related to the 2018 PQRS payment adjustment, which will be based on EP or group practice reporting of quality measures during calendar year 2016. CMS states that it focused on aligning requirements with other quality programs, including the Medicare EHR Incentive Program for EPs, the VM, and the Medicare Shared Savings Program. (CMS notes that under MACRA, the PQRS ends in 2018 to be replaced by the new Merit-based Incentive Payment System (MIPS), which may incorporate aspects of PQRS.) As discussed in section III.I.6 below, CMS seeks comments related to the MIPS and other MACRA changes.

1. **Clarification of Eligible Professionals for Purposes of PQRS Participation**

2015 is the first year of the PQRS payment adjustment, during which EPs who did not satisfactorily report PQRS data during 2013 are receiving a 1.5 percentage point negative adjustment on all Part B covered professional services under the PFS. (For 2016 and thereafter, the negative adjustment for not satisfactorily reporting PQRS measures is 2.0 percentage points.) Noting that it has received numerous queries about how to avoid the PQRS payment adjustment, CMS clarifies who is required to participate in PQRS for purposes of the payment adjustments in the proposed rule. Specifically:

• No hardship or low volume exemptions are provided for the PQRS payment adjustment.

• The definition of eligible professional is re-stated. (See footnote in item II.H.2 above.)

• Due to a change in how EPs in Critical Access Hospitals billing under Method II are reimbursed by Medicare, these EPs may participate in PQRS using all reporting mechanisms available, including claims-based reporting.
• Due to the way they bill for services, EPs who practice in Federally Qualified Health Centers, Rural Health Clinics, Independent Diagnostic Testing Facilities and Independent Laboratories, would not be subject to the PQRS adjustment.

2. Requirements for PQRS Reporting Mechanisms

The PQRS includes several reporting mechanisms: claims, qualified registry; EHR (both direct and data submission vendor products); Group Practice Reporting Option (GPRO) web interface; certified survey vendors for the CAHPS for PQRS measures; and the QCDR. In this rule, CMS proposes changes to the QCDR and qualified registry reporting mechanisms. No changes are proposed for the others. Audit requirements are proposed for any vendor submitting quality measures for the PQRS.

Changes to QCDR Requirements. CMS reviews the definition of a QCDR at §414.90(b) as one that has self-nominated and successfully completed a qualification process showing that it collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. The following functions must be provided: submit quality measures data or results to CMS to demonstrate that its EPs have satisfactorily participated in PQRS; have in place mechanisms for transparency of data elements and specifications, risk models, and measures; submit to CMS quality measures data on multiple payers, not just Medicare; provide timely feedback to participating EPs at least four times a year on the reported measures; possess benchmarking capacity that compares quality of care among EPs performing similar functions. While CMS has enumerated requirements for becoming a QCDR in previous rulemaking, as long as an entity meets the basic definition of a QCDR it is encouraged to self-nominate to become one.

In this rule, CMS indicates that it will expand the self-nomination period, and proposes to modify existing requirements for QCDRs. Specifically:

• CMS will open the self-nomination QCDR period on December 1 of the prior year to allow entities more time to self-nominate. Previously, CMS adopted January 31 of the qualification year as the deadline for self-nominations. No opening date was specified, but CMS has generally opened the self-nomination period on January 1 of that year.
• Beginning in 2016, CMS proposes to modify the requirement for establishment of a QCDR entity to specify that the entity must be in existence on January 1 of the year for which it seeks to be a QCDR (e.g., January 1, 2016 for purposes of 2016 data collection.) CMS says it has received feedback that the current requirement for an entity to be in existence on January 1 of the previous year is overly burdensome and delays participation of qualified entities.
• In lieu of the required signed, written email attesting to data accuracy and completeness, beginning in 2016, a QCDR would attest during the data submission period using a web-based check box on the QualityNet PQRS portal at https://www.qualitynet.org/portal/server.pt/community/pqri_home/212.
• The deadline for providing measure information would be moved up from March 31 to January 31 of the year in which the entity seeks to become a QDCR. That is, all documents necessary to analyze an entity’s qualifications must be provided to CMS at
the time of self-nomination. CMS says this is necessary because it has experienced issues with the measure data received for the 2013 reporting year that prompt it to more closely examine the measures to determine whether an entity is fully ready and qualified to participate as a QCDR. The information to be submitted includes the data validation plan and measure specifications for any non-PQRS measures that the entity intends to report. Information submitted by January 31 for the purposes of qualification could not be changed subsequently; although supplemental information could be provided if requested by CMS.

- Additional data validation requirements are proposed for QCDRs beginning in 2016. At the time of self-nomination the entity would have to provide information on methods by which measure numerator and denominator data is obtained from customers (e.g., claims web tools, EHRs); method used to verify accuracy of each TIN and NPI it intends to submit; method to accurately calculate reporting rates and performance rates for measures and measure groups, including methodology for composite measures and those with multiple performance rates; the process for randomized audit of a subset of data prior to submission to CMS; information on the sampling methodology, if applicable; and the process for completing a detailed audit if the validation reveals inaccuracy and how this information will be conveyed to CMS. QCDRs would perform the validation outlined in the validation strategy and send evidence of successful results to CMS. The 2016 Data Validation Execution Report would be due by June 30 of the year in which the reporting period occurs (June 30, 2016 for reporting periods occurring during 2016).

- QCDRs would have the ability to submit quality measures for group practices. As noted earlier, CMS proposes in this rule to create an option for group practices to report quality measures via a QCDR, as permitted by MACRA.

Changes to Requirements for Qualified Registries. For qualified registries, CMS proposes changes regarding attestation statements that are identical to those described above for QCDRs. With respect to data validation, the requirements proposed above for QCDRs are also proposed to apply to qualified registries, along with three additional proposed requirements:

- The registry would describe how it would verify that EPs or group practices report on at least 1 measure contained in the cross-cutting measure set if the EP/group practice sees at least 1 Medicare patient in a face-to-face encounter. Included would be a description of how the entity plans to verify that the data provided is complete and contains the entire cohort of data.
- The registry would describe the method that it would use to verify that only the measures in the applicable PQRS Claims and Registry Individual Measure Specifications would be used for submission.
- The registry would maintain the ability to randomly request documentation from providers to verify accuracy of data, and would have to provide CMS access to review the Medicare beneficiary data on which PQRS submissions are based, or provide to CMS a copy of the actual data if requested for validation purposes.

Auditing of Entities Submitting PQRS Quality Measures Data. CMS states that it is in the process of auditing PQRS participants and proposes that beginning in 2016, any vendor submitting quality measures for the PQRS must make available to CMS the contact information
(at a minimum the phone number, address, and email) of each EP on behalf of whom it submits
data, and must retain all data submitted to CMS for the PQRS program for a minimum of seven
years.


CMS proposes the following satisfactory reporting criteria for individual EPs for the 2018 PQRS payment adjustment. These requirements are consistent with the 2017 requirements, and appear in §414.90(j) of the proposed regulatory text, or §414.90(k) with respect to QCDR reporting.

Reporting 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.

Reporting Via EHR Direct Product or EHR Data Submission Vendor

Report 9 measures covering at least 3 NQS domains. If an EP’s certified EHR technology 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.

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.

EPs submitting less than 9 measures would again be subject to the measure application validity (MAV) process to allow CMS to determine whether the EP should have reported quality data codes for additional measures. (Additional information on the MAV process is available on the CMS PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html. The MAV process also allows the agency to determine whether an EP or group practice should have reported on any of the cross-cutting measures.

With respect to the issue of face-to-face encounters (relevant for reports via claims or qualified registry), CMS proposes no changes from current policy under which it determines 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. Telehealth visits are not counted as face-to-face encounters for purposes of the cross-cutting-measure reporting requirement. A list of face to face encounter codes for the cross-cutting measure requirement is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/FacetoFace_Encounter_CodeList_01302015.zip

Via QCDR

CMS proposes to apply to the 2018 payment determination the same criteria adopted for satisfactory QCDR participation for the 2017 PQRS payment adjustment, which appears in regulatory text in §414.90(k):

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.


CMS proposes the criteria for satisfactory reporting for group practices participating in the GPRO for the 2018 PQRS payment adjustment. These are included in Table 21 in the proposed rule an abbreviated version of which is reproduced below. In general, the requirements are unchanged from the 2017 requirements. However, CMS proposes to expand the group practices which are required to report the CAHPS for PQRS survey to include those with 25 or more EPs, and changes are also made to reflect the proposed policy to permit QCDR reporting for group practices participating in the GPRO.

CAHPS for PQRS Survey. CMS proposes to modify the group practices which would be required to report the CAHPS for PQRS survey to include group practices of 25 or more EPs that register to participate in the GPRO and select the GPRO web interface as the reporting mechanism. These group practices would be required to select and pay for a CMS-certified survey vendor to report the CAHPS for PQRS. (For 2015 reporting, group practices of 100 or more EPs that register to participate in the GPRO were required to select a CMS-certified survey vendor to report the CAHPS for PQRS, regardless of the reporting mechanism selected.) Under the proposal, group practices that report using the qualified registry, EHR, or QCDR reporting mechanisms would not be required to report the CAHPS for PQRS. CMS says this is because it has discovered that group practices reporting through these mechanisms may be highly specialized or otherwise unable to report the CAHPS survey. CAHPS for PQRS reporting would be an option for all group practices, however.

Recognizing that the proposed requirement may cause concern for smaller group practices who choose to participate in PQRS through the GPRO web interface but who have not yet
administered the CAHPS for PQRS Survey, CMS reviews CAHPS requirements and addresses questions it has received since the introduction of the survey measure regarding its administration, including identifying a focal provider and CMS beneficiary sample selection. More information on CAHPS for PQRS is available at [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/CMS-Certified-Survey-Vendor.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/CMS-Certified-Survey-Vendor.html).

QCDR Reporting for Group Practices. As noted earlier, CMS proposes (consistent with MACRA) to allow group practices to use a QCDR to participate in the PQRS. CMS proposes to use the same criteria for satisfactory reporting through a QCDR for group practices as applies to EPs. For the 2018 PQRS payment adjustment, CMS proposes a 12 month reporting period of calendar year 2016. CMS notes that a 12-month calendar period is preferable to a 6-month period because the data collected provide a more accurate assessment and because the full year would be used with regard to the group practice’s participation in the QCDR.

<table>
<thead>
<tr>
<th>Group Practice Size</th>
<th>Measure Type</th>
<th>Reporting Mechanism</th>
<th>Satisfactory Reporting Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>25+ EPs (if CAHPS for PQRS does not apply)</td>
<td>Individual measures in the GPRO Web Interface</td>
<td>GPRO Web Interface</td>
<td>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 the group practice must report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.</td>
</tr>
<tr>
<td>25+ EPs (if CAHPS for PQRS applies)</td>
<td>Individual measures in the GPRO Web Interface + CAHPS for PQRS</td>
<td>GPRO Web Interface + CMS-certified survey vendor</td>
<td>The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must 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 must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.</td>
</tr>
</tbody>
</table>
| 2+ EPs | Individual measures | Qualified registry | Report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the PQRS cross-cutting measure set. If less than 9 measures covering at
### TABLE 21 (abbreviated): Summary of Proposed Requirements for the 2018 PQRS Payment Adjustment: Group Practice Reporting Criteria for Satisfactory Reporting of Quality Measures Data via the GPRO

(In each case, a 12-Month Reporting Period of January 1- December 31, 2016 is proposed)

| 2+ EPs that elect CAHPS for PQRS | Individual measures+ CAHPS for PQRS | Qualified registry+ CMS-certified survey vendor | The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. 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 PQRS crosscutting measure set. |
| 2+ EPs | Individual measures | Direct EHR Product or EHR Data Submission Vendor Product | Report 9 measures covering at least 3 domains. If the 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 all of 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. |
| 2+ EPs that elect CAHPS for PQRS | Individual measures+ CAHPS for PQRS | Direct EHR Product or EHR Data Submission Vendor Product+ CMS-certified survey vendor | The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is Medicare patient data. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data. |
| 2+ EPs | Individual PQRS and/or non-QCDR | QCDR | Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the group practice’s patients. Of these measures, the group practice would report |
TABLE 21 (abbreviated): Summary of Proposed Requirements for the 2018 PQRS Payment Adjustment: Group Practice Reporting Criteria for Satisfactory Reporting of Quality Measures Data via the GPRO
(In each case, a 12-Month Reporting Period of January 1- December 31, 2016 is proposed)

| PQRS measures | 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. |

With respect to reporting via the GPRO web interface, 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. For assigning patients to group practices reporting via the GPRO web interface, CMS proposes to continue for the 2018 PQRS payment adjustment and future years the methodology used for the 2017 PQRS payment adjustment, which is the methodology used within the VM for the claims-based quality measures and cost measures.

5. PQRS Quality Measures for 2016 and Beyond for EPs and Group Practices

CMS discusses the measure selection process for PQRS, the role of the six National Quality Strategy (NQS) domains, 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. Noting that measure specifications and measure titles may change as a result of the National Quality Forum endorsement process or as part of an effort to align measures across quality programs, CMS refers readers to the Specifications Manual and notices also available on that web page.

The proposed rule includes the following tables of PQRS measures (not reproduced in this summary). In each case the table describes the measure and includes rationales for the proposed measure changes:

Table 22 lists 4 measures that CMS proposes to add to the PQRS cross-cutting measure set for 2016 reporting and beyond. The set currently consists of 19 measures. The proposed new measures involve alcohol screening, breast cancer screening, risk assessment for falls, and a plan of care for falls. Except for the alcohol screening measure, these are existing PQRS measures.

Table 23 lists 45 proposed new PQRS measures to begin with 2016 reporting. The table includes the Measure Applications Partnership (MAP) recommendation. CMS notes that while it always considers the MAP recommendation, sometimes it believes that the rationale outweighs any concerns of the MAP.

Table 24 lists 5 PQRS measures for which CMS proposes to change the NQS domain assignment.
Table 25 lists 12 PQRS measures that CMS proposes to remove from the PQRS beginning in 2016, and provides a rationale for the proposal.

Table 26 lists 18 PQRS measures for which CMS propose changes to the way in which the measures may be reported beginning in 2016.

CMS proposes to add three new measures groups to PQRS beginning in 2016. In some cases these include existing PQRS measures, while in other cases new measures are proposed, and also included in Table 23 above. The three measures groups are:

- Cardiovascular Prevention Measures Group (Million Hearts) (Table 27)
- Diabetic Retinopathy Measures Group (Table 28)
- Multiple Chronic Conditions Measures Group (Table 29)

With respect to the Cardiovascular Prevention Measures Group, CMS notes that such a group was included in the PQRS prior to 2015 but was removed due to clinical guideline changes affecting many of the measures. (In 2014 the group included PQRS measures 2, 204, 226, 236, 241 and 317) CMS is re-proposing this group, supported by the Million Hearts Initiative, with an adjustment to align with current clinical guidelines.

Specific additions and deletions of measures beginning in 2016 are proposed for four measures groups:

- Dementia Measures Group (Table 29B)
- Diabetes Measures Group (Table 29C)
- Preventive Care Measures Group (Table 29D)
- Rheumatoid Arthritis Measures Group (Table 29E)

The proposed rule also includes Table 29A listing the measures in the Coronary Artery Bypass Graft Measures Group for 2016, but CMS does not indicate what change is proposed. The seven measures listed appear to be those that are included in the CABG measures group for 2015.

Table 30 reflects the proposed addition of one new measure to the measures available for reporting in the GPRO web interface beginning in 2016: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.

6. Request for Input on Provisions Included in MACRA

CMS seeks comments on several provisions of MACRA. Section 101(c) requires creation of the Merit-based Incentive Payment System (MIPS) to begin with 2019 payment. EPs (initially including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) will receive annual payment increases or decreases based on their performance in a prior period; the PQRS and other performance programs will be consolidated under the MIPS.

CMS seeks comments on certain aspects of the MIPS, but the invitation for comments is not limited to these areas:
Low-volume threshold: The Secretary is directed to select a low-volume threshold to apply for purposes of excluding certain EPs from the definition of a MIPS EP. The low-volume threshold may include one or more or a combination of the following: (1) the minimum number of Medicare beneficiaries who are treated by the; (2) the minimum number of items and services furnished to Medicare beneficiaries by such professional; and (3) the minimum amount of allowed charges billed by such professional under Medicare Part B.

CMS seeks comments on what would be an appropriate low-volume threshold for the MIPS. This includes whether a low-volume threshold should be established using one factor or a combination of factors, and on which factors to include, individually or in combination. Additionally, CMS is interested in the applicability to the MIPS of low-volume thresholds used in other CMS reporting programs (such as the one set for the Medicaid EHR Incentive Program under section 1903(t)(2) of the Act). CMS says it may consider proposing a similar threshold, such as excluding from the MIPS EPs that do not have at least 10 percent of their patient volume derived from Medicare Part B encounters. It specifically seeks comments as to whether this would be an appropriate low-volume threshold.

Clinical practice improvement activities: MACRA specifies clinical practice improvement activities as one of the performance categories used in determining the composite performance score under the MIPS. These are defined as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, are likely to result in improved outcomes. At least the following subcategories if clinical practice improvement must be included:

1. Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
2. Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.
3. Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.
4. Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
5. Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.
6. Participation in an alternative payment model.

CMS seeks comment on what activities could be classified as clinical practice improvement activities according to this definition.

Alternative Payment Models

Section 101(e) of MACRA, provides a framework for promoting and developing alternative payment models (APMs) and providing incentive payments for eligible professionals who participate in APMs. The statutory amendments made by this section have payment implications
for eligible professionals beginning in 2019, and CMS is broadly seeking public comment on the
topics in this section through this proposed rule.

While CMS says it will publish a Request for Information (RFI) regarding the section
101(e) amendments, and there will be further opportunity for comment during future
rulemaking, at this time comments are welcome on approaches to implementation. Topics
that will be included in the RFI include: the criteria for assessing physician-focused payment
models; the criteria and process for the submission of physician-focused payment models eligible
APMs, qualifying APM participants; the Medicare payment threshold option and the
combination all-payer and Medicare payment threshold option for qualifying and partial CMS-
qualifying APM participants; the time period to use to calculate eligibility for qualifying and
partial-qualifying APM participants, eligible APM entities, quality measures and EHR use
requirements; and the definition of nominal financial risk for eligible APM entities.

7. Collection of Information Requirements and Impact Analysis

CMS anticipates an increase in the rate of EP participation in the PQRS. In 2013, 51 percent of
EPs (about 642,000) participated; a 70 percent rate is estimated for 2016 (2018 PQRS payment
adjustment). More EPs are expected to participate in PQRS through qualified registries or
QCDRs in 2016. The number of QCDRs is estimated to grow from 50 to 60, and the number of
EPs reporting through either registries or QCDRs is estimated to be 212,000. About 68,000 EPs
used clinical registries for PQRS reporting in 2013; CMS says no data are yet available on the
QCDR option usage, which began in 2014.

Aggregate costs in 2016 to EPs resulting from PQRS reporting are estimated to range from $160
million to $470 million. The lower estimate assumes that EPs will participate in PQRS to avoid
the payment adjustment, while the upper end assumes that they will participate for the purposes
of earning an incentive as well. Under the discussion of collection of information requirements,
CMS provides detailed estimates of the compliance costs associated with the various PQRS
reporting mechanisms. 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 EP or group practice will spend 5 hours to get ready to
participate in PQRS for the first time, for a total estimated cost of $133.40.

With respect to PQRS reporting via claims, CMS assumes that the time needed to perform all the
steps necessary to report each PQRS measure will range from 0.25 minutes to 12 minutes, and
that a physician will report data for an average of 6 cases for each of the 9 measures, meaning
that the total cost of claims-based reporting will range from $18.90 to $906.66, with the cost to
the median practice estimated at $132.30 per EP. CMS estimates that about 350,000 EPs will
participate in the PQRS using the claims-based reporting mechanism in 2015. The aggregate cost
is estimated to range from $53 million to $364 million, with a median estimate of $93 million.

CMS estimates that the remainder of the EPs will participate in PQRS using either the qualified
registry or qualified clinical data registry options (212,000 EPs combined), EHR-based reporting
(50,000 EPs), or the GPRO web interface reporting mechanism (500 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 $160. 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 $6,632. Regarding the proposed requirement that group practices with 25 or more EPs must report CAHPS for PQRS, CMS does not believe it changes the burden on group practices because it considers reporting the CAHPS for PQRS survey as reporting three measures covering one domain in meeting the overall reporting requirement.

J. Electronic Clinical Quality Measure (eCQM) and Certification Criteria; EHR Incentive Program-Comprehensive Primary Care Initiative and Medicare Meaningful Use Aligned Reporting

In the 2015 PFS final rule CMS finalized that, beginning in 2015, EPs are not required to ensure that their certified EHR Technology (CEHRT) products are recertified to the most recent version of the electronic specifications for the clinical quality measures (CQMs). Nevertheless, EPs must still report the most recent version of the electronic specifications for the CQMs if they choose to report CQMs electronically for the Medicare EHR Incentive Program.

CMS discusses the certification proposals made by HHS’ Office of the National Coordinator for Health Information Technology that were included in the FY 2016 IPPS proposed rule (80 FR 24611 through 24615), including for the certification criterion for “CQMs – report” an optional certification for EHRs per the “form and manner” CMS requires for electronic submission to participate in the EHR Incentive Programs and PQRS in addition to QRDA Category I (individual patient-level report) and QRDA Category III (aggregate reports). That proposed rule also anticipated related proposals in this rule. (Note: “QRDA” stands for Quality Reporting Document Architecture.)

Accordingly, CMS proposes to modify the regulatory text at §495.4 to require that providers participating in PQRS and the EHR Incentive Programs under the 2015 Edition possess EHRs that have been certified to report CQMs according to the format that CMS requires for submission. Specifically, the CEHRT definition for 2015 through 2017 would be modified to require that EHR technology be certified to report CQMs, in accordance with the optional portion of the 2015 Edition CQM reporting criterion certification, in the format that CMS can electronically accept (CMS’ “form and manner” requirements) if certifying to the 2015 Edition “CQMs – report” certification criterion at §170.315(c)(3). Specifically, this would require technology to be certified to §170.315(c)(3)(i) (the QRDA Category I and III standards) and
§170.315(c)(3)(ii) (the optional CMS “form and manner”). CMS notes that the proposed CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule published on March 30, 2015 (80 FR 16732 through 16804) allows providers to use 2014 Edition or 2015 Edition certified EHR technology. These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

Additionally, CMS proposes to revise the CEHRT definition for 2018 and subsequent years to continue the proposed requirement that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept. Specifically, this would require technology to be certified to §170.315(c)(3)(i) (the QRDA Category I and III standards) and §170.315(c)(3)(ii) (the optional CMS “form and manner”). These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

K. Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

The CPC initiative is a multi-payer initiative promoting collaboration between public and private health care payers to strengthen primary care that began on October 1, 2012 and is scheduled to end on December 31, 2016. This initiative is being implemented in seven regions: statewide in Arkansas, Colorado, New Jersey, and Oregon; and regionally in Capitol District Hudson Valley, New York; Cincinnati-Dayton Region, Ohio/Kentucky; and Greater Tulsa, Oklahoma. There are approximately 480 participating practices and 38 participating payers.

In the CPC initiative, in addition to the usual FFS payments that practitioners receive for furnishing services to their Medicare patients, practices receive a monthly non-visit based care management fee for each Medicare FFS beneficiary, and in cases where the state Medicaid agency is participating, for each Medicaid FFS beneficiary. Monthly payments for each Medicare beneficiary averaged $20 per beneficiary per month during years 1 and 2 of the initiative (2013 and 2014) and average $15 per beneficiary per month in years 3 and 4 (2015 and 2016). Practices also receive non-visit based care management payments from other participating CPC payers and the practices are expected to use these payments to support a “whole-practice care delivery transformation strategy”. CPC practices also have the opportunity to share net savings; for each performance period (2014, 2015 and 2016) CMS calculates savings to the Medicare program generated by all CPC practices within each region, taken as a group. A portion of any savings at the level of each region will be distributed to practices in that region according to performance on quality metrics (patient experience measures, claims-based measures and eCQMs). Practitioners participating in the CPC initiative may not bill Medicare for CCM services furnished to patients attributed to the practice for purposes of the practice’s participation; CMS considers these would be duplicative payment to the per beneficiary per month payment under the CPC.

The payment model is designed to support practices providing the following five comprehensive primary care functions: risk stratified care management, access and continuity, planned care for chronic conditions and preventive care, patient and caregiver engagement, and coordination of care across the medical neighborhood. Participating practices must demonstrate progress towards the provision of the five comprehensive primary care functions by meeting nine annual Milestones: budget, care management for high risk patients, access and continuity, patient
experience, quality improvement, care coordination across the medical neighborhood, shared
decision making, participate in learning collaborative, health information (full requirements of
each Milestone are available at http://innovation.cms.gov/Files/x/CPCI-Implementation-

The first independent evaluation report of the CPC initiative was released on January 23, 2015.
CMS notes the evaluator’s report concluded that in the first four payment quarters the initiative
appeared to reduce total monthly Medicare Parts A and P expenditure per beneficiary (absent the
CPC initiative) by $14, or 2 percent, without including the care management fees paid.
According to CMS, these results suggest that CPC has generated nearly enough savings in
Medicare health expenditures to offset care management fees. There were also statistically
significant declines in hospitalization and emergency department utilization. The report did note
that expenditures and service use impact estimates differed significantly across regions and there
were no statistically significant impacts in quality measurements. Further information about the
CPC initiative and the independent evaluation report are at

Considerations for Potential Model Expansion

The CPC initiative is undertaken by CMMI under the authority of Section 1115A(b) of the Act,
as added by section 3021 of the ACA. Section 1115A(c) gives the Secretary authority to expand
the duration and scope of successful models tested under section 1115A(b), including
implementation on a nationwide basis. Such expansion must go through rulemaking and is only
applicable to models for which these findings are made, taking into account the evaluation of the
model required under section 1115A(b)(4):

1. The Secretary determines that the expansion is expected to either reduce Medicare
   spending without reducing the quality of care or improve the quality of patient care
   without increasing spending;
2. The CMS Chief Actuary certifies that the expansion would reduce (or would not result in
   any increase in) net Medicare program spending; and
3. The Secretary determines that the expansion would not deny or limit the coverage or
   provision of Medicare benefits.

CMS is not proposing to expand the CPC initiative at this time. The primary goal for this
solicitation of public comments is to obtain information about issues related to potential
expansion of the CPC initiative. CMS notes they make use this feedback to modify existing
models or test additional models. CMS notes they would use additional rulemaking if they
decide to expand the initiative.

CMS seeks input on these issues:

- **Practice readiness**: What proportion of primary care practices are ready to reorganize
  their work flows to accomplish the required five comprehensive primary care functions
  and whether readiness varies based on different practice structures (e.g. small primary
care practices, multi-specialty practices and employed primary care practices within
integrated health systems)?
• **Practice standards and reporting:** The value and operational burden of the CPC Milestones approach, including the current system of quarterly reporting via a web portal.

• **Practice groupings:** Whether any potential expansion should be limited to existing CPC regions or include new geographic regions. Whether multi-site group practices would be willing to involve all their primary care sites in a potential expansion of the CPC initiative (current sites participating in the CPC initiative were individually selected) and how these practices could best be grouped for calculating shared savings.

• **Interaction with state primary care transformation initiatives:** Whether a potential expansion could and should exist in parallel in a state with a separate state-led primary care transformation effort, especially if Medicare is participating in that effort.

• **Learning activities:** What support practices would require to provide the five comprehensive primary care functions and the readiness of the private sector to respond to the need for this support. What is the willingness and ability of existing state and regional primary care or patient centered medical home learning collaboratives to support practices in a potential expansion?

• **Payer and self-insured employer readiness:** Whether current participating payers would expand their current investment and the readiness of new payers, including self-insured employers, to participate. Whether there should be a minimum threshold for payer participation, or at the level of an individual practice, in order for a payer to be eligible for participation. Information about the best methods for payers to engage with one another, participating practices, and CMS.

• **Medicaid:** Whether state Medicaid agencies would be willing to participate in a potential expanded CPC initiative for their fee-for-service enrollees and whether Medicaid managed care plans would be willing to participate in a potential expansion.

• **Quality reporting:** Comments on practice readiness to report eCQMs and payer interest in using practice site level data rather than their own enrollees’ information for performance based payments.

• **Interaction with the CCM fee:** How payment for CCM services might interact with a potential expansion of the CPC initiative and affect practice interest in participation.

• **Provision of data feedback to practices:** CMS currently sends quarterly feedback report to practices including cost and utilization information for the Medicare FFS attributed population to the practice. Whether there is better data to support quality improvement and promote attention to total cost.

### L. Medicare Shared Savings Program

With respect to the Medicare Shared Savings Program involving accountable care organizations (ACOs), the proposed rule proposes changes to the quality measures, seeks comments related to the use of health information technology and proposes revisions to the assignments of beneficiaries.

#### 1. Quality Measures and Performance Standards

CMS proposes to add one measure to the Preventive Health domain, Statin Therapy for the Prevention and Treatment of Cardiovascular Disease. This measure would replace the low-
density lipid control measures previously retired from the measure set. The total number of measures would increase from 33 to 34 measures (Table 31 lists the quality measure set).

**a. Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**

This measure was developed by CMS in collaboration with other federal agencies and the Million Hearts® Initiative. According to CMS, the measure is intended to support the prevention and treatment of cardiovascular disease by measuring the use of statin therapies according to updated clinical guidelines for patients with high cholesterol. The measure was reviewed by the NQF Measure Applications Partnership (MAP) and the MAP encouraged further development (Measure Under Consideration (MUC) ID: X3279)

The measure reports the percentage of beneficiaries who were prescribed or were already on statin medication therapy during the measurement year and who fall into any of the following three categories:

1. High-risk patients aged ≥ to 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD);
2. Adult patients aged ≥ to 21 years with any fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) that is ≥ 190 mg/dL; or
3. Patients added 40 to 75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 170-189 mg/dL who were prescribed or were already on statin medication therapy during the measurement year.

CMS proposes the following for implementing this measure:

- *Equally weight* the multiple denominators when calculating the performance rate.
- *Increase the size* of the oversample of this measure from the normal 616 beneficiaries for CMS web interface reporting to 750 or more beneficiaries. CMS notes this would account for reporting on multiple denominators and to ensure a sufficient number of beneficiaries meet the measure denominators for reporting.
- Consider the measure as *pay for reporting for 2 years* and then phase the measure into *pay for performance in the third year* of the agreement period.
- *Include this measure in the Preventive Health domain.*

CMS also seeks comment whether the measure should be considered a single measure or multiple measures for reporting and benchmarking.

**b. Domains Within the Quality Performance Standard**

Table 32 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes, including the proposed addition of the Statin Therapy quality measure in the Preventive Health domain. Each of the four domains, equally weighted at 25%, will include the following number of quality measures:

- Patient/Caregiver Experience of Care – 8 measures
- Care Coordination/Patient Safety – 10 measures
- Preventive Health – 9 measures
- At Risk Population – 7 measures (including 6 individual measures and a 2-component diabetes composite measure)
With the proposed addition of the Statin Therapy quality measure, the total possible points for the Preventive Health domain would increase from 16 to 18 points. Related to CMS’ request about whether the measure should be a single or multiple measures, CMS seeks comment on how to score the Statin Therapy quality measure. CMS notes that the measure could be scored as 3 points, 1 point for each of the three domains.

c. Proposed Policy for Measures No Longer Aligning with Clinical Guidelines, High Quality Care or Outdated Measures May Cause Patient Harm

CMS is proposing to adopt a general policy to maintain measures as pay-for-reporting, or revert pay-for-performance measures to pay-for-reporting measures, if the measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or when clinical evidence suggests that continued measure compliance and collection of the data may result in patient harm. CMS believes this proposed policy would enable them to respond more quickly to needed changes without waiting for a future rulemaking cycle to retire a measure or revert to pay for reporting. CMS would implement any necessary changes to the measure in the next rulemaking cycle by either retiring the measure or maintain it as pay for reporting.

d. Request for Comments Related to the Use of Health Information Technology (HIT)

CMS believes that measures which encourage the effective adoption and use of HIT among ACO participants is important for successful ACOs. CMS is not proposing any changes to the current measure “Percent of PCPs who Successfully Meet Meaningful Use Requirements” (ACO-11).

CMS seeks comment on how to modify this measure to incentivize and reward providers to use more advanced HIT:

- Should this measure be expanded to include all EPs, including specialists?
- How could the current measure be updated to reward providers who have achieved higher levels of HIT adoption?
- Should CMS substitute or add another measure that would focus specifically on the use of HIT, rather than meeting overall Meaningful Use requirements (e.g. the transitions of care measure required for the EHR Incentives Program)?
- What other measures of IT-enabled processes would be most relevant to participants within ACOs and how can the administrative burden on providers be minimized in collecting these measures?

e. Conforming Changes to Align with PQRS

CMS proposes to revise to §425.504(a) to replace the phrase “ACO providers/suppliers who are EPs” and “ACO providers/suppliers that are EPs” with the phrase “EPs who bill under the TIN of an ACO participant” along with conforming changes anywhere the term ACO providers/suppliers appear in §425.504. CMS believes these changes clarify the requirement that the ACO report on behalf of these EPs applies in a way that is consistent with the PQRS GPRO policies and also addresses mid-year updates to and deletions from the ACO provider/supplier list. CMS notes this change clarifies that an ACO must still report quality data for services billed under the TIN of an ACO participant by an EP that was an ACO provider/supplier for a portion of the performance year.
2. Assignment of Beneficiaries to ACOs

a. Assignment of Beneficiaries Based on Certain E/M Services in SNFs
CMS discusses comments it received objecting to inclusion of SNF visit codes (CPT codes 99304-99318) as primary care services considered in the beneficiary assignment process. Commenters believed a SNF is more of an extension of the hospital inpatient setting rather than a component of the community based primary care setting and that ACOs are often inappropriately assigned patients with long SNF stays and whom the ACO has no clinical contact after the ACO stay. Commenters suggested that CMS make a distinction between E/M services provided in two different places of service POS 31 (SNF) and POS 32 (NF) and suggested exclusion of SNF visit codes furnished in POS 31.

CMS agrees with the commenters and proposes to amend the definition of primary care services at §425.20, for purposes of the Shared Savings Program, to exclude services billed under CPT codes 99304-99318 when the claim includes the POS 31 modifier. If finalized, CMS anticipates applying this revised definition for purposes of determining ACO eligibility during the application for the 2017 performance year, which occurs during 2016, and the revision would be applicable for all ACOs starting with the 2017 performance year. Based on preliminary analysis, CMS does not expect removal of these claims from the assignment process will result in a significant reduction in the number of beneficiaries assigned to ACOs. CMS does recognize, however, that assignment to some ACOs may be more affected than others.

b. Assignment to Beneficiaries that Include ETA Hospitals
Electing Teaching Amendment (ETA) hospitals are hospitals that under section 1861(b)(7) if the Act and §415.160 have voluntarily elected to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in lieu of Medicare PFS payments that might otherwise be made for these services. These institutional claims do not include allowed charges, which are necessary to determine where a beneficiary received the plurality of primary care services. CMS uses the amount that would otherwise be payable under the PFS for the applicable HCPSC code, in the applicable geographic area as a proxy for the allowed charges for the service.

CMS notes they implemented a change in coding policy under the OPPS that inadvertently affects the assignment of beneficiaries to an ACO when the beneficiary receives care at an ETA hospital. Effective for services furnished on or after January 1, 2014, outpatient hospitals, including ETA hospitals, were instructed to use HCPCS code G0463 instead of CPT codes 99201-99205 and 99211-99215. CMS proposes to use the weighted mean amount payable for CPT codes in the range of 99201-99205 and 99211-99215 as a proxy for the amount of the allowed charges for G0463 when submitted by ETA hospitals. The weights needed to impute the weighted mean PFS payment rate for G0463 would be derived from the relative number of services furnished at the national level for the range of CPT codes. CMS will provide additional details about computation of the proxy amount for G0463 through sub-regulatory guidance.

CMS proposes to consider HCPCS code G0463 when submitted by ETA hospitals as a code designated as a primary care service for purposes of the Shared Savings Program and proposes that this change will be applicable for the 2016 and subsequent performance years.
CMS also proposes to amend the definition of primary care services at §425.20 to reflect this change and to revise §425.402 to make conforming changes. In addition, CMS proposes to amend §425.102(a) to add ETA hospitals to the list of ACO participants that are eligible to form an ACO that may apply to participate in the Shared Savings Program.

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

Beginning January 1, 2015, the Secretary was 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 (EP).5

Since beginning to apply the VM to Medicare PFS payments, CMS has phased-in the VM in the following sequence:

- Starting January 1, 2015, the VM applied to physicians in groups of 100 or more EPs.
- Starting January 1, 2016, the VM applies to physicians in groups of 10 or more EPs.
- Starting January 1, 2017 the VM applies to physicians in groups of 2 or more EPs and to physicians solo practitioners.
- Starting January 1, 2018, the VM applies to nonphysician EPs in groups with 2 or more EPs and to nonphysician EPs who are solo practitioners.

In this rule, CMS is proposing to apply the VM in the 2018 payment adjustment period to nonphysicians EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs) and certified registered nurse anesthetists (CRNAs) in groups with two of more EPs and to those who are solo practitioners and not to other types of professionals who are nonphysician EPs.

1. Proposals for the VM

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

- Group Size:
  - Beginning with the 2016 payment adjustment period, a TIN’s size would be determined based on the lower of the number of EPs indicated by the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) generated list or CMS’ analysis of the claims data for purposes of determining the payment adjustment under the VM.
- Application of the VM to Nonphysicians EPs
  - Beginning with the 2018 payment adjustment period, apply the VM to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs in groups and those who

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5 Physicians are defined in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

6 Eligible professionals are defined in section 1848(k)(3)(B) of the Act as any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act: physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse mid-wife, clinical social worker, clinical psychologist, registered dietician, or nutritional professional; (3) a physician or occupational therapist or qualified speech-language pathologist; or (4) a qualified audiologist.
are solo practitioners and not to other types of professionals who are nonphysician EPs; and
  o For the 2018 payment adjustment period, the VM would not apply to groups and solo practitioners if either the PECOS list or claims analysis shows that the groups of solo practitioners consist only of nonphysician EPs who are not PAs, NPs, CNSs, and CRNAs.

- Setting the VM Adjustment Based on PQRS Participation
  o Continue to apply a two-category approach for the 2018 VM based on participation in the PQRS by groups and solo practitioners; and
  o For the 2018 payment adjustment period, apply the quality-tiering methodology to all groups and solo practitioners in category 1. Groups and solo practitioners will be subject to upward, neutral, or downward adjustments under quality-tiering methodology; except as finalized in the 2015 final rule, groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments.

- Application of the VM to Participants in ACOs under the Shared Savings Program
  o Beginning with the 2017 payment adjustment period, apply the VM adjustment percentage for groups and solo practitioners that participate in two or more ACOs during the applicable period based on the performance of the ACO with the highest quality composite score;
  o For the 2018 payment adjustment period, apply the VM to groups and solo practitioners that participate in an ACO during the applicable performance period regardless of whether any EPs in the group or the solo practitioner also participated in an Innovation Center model during the performance period;
  o For the 2018 payment adjustment period, if the ACO does not successfully report quality data as required by the Shared Savings Program, all groups and solo practitioners participating in the ACO will be in Category 2 for the VM and will be subject to a downward payment adjustment; and
  o Beginning with the 2017 payment adjustment period, apply an additional upward payment adjustment of +1.0x to ACO participant TINs that are classified as “high quality” under the quality-tiering methodology, if the participating ACO has an attributed patient population with an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scored nationwide as determined under the VM methodology.

- Application of the VM to Participants in the Pioneer ACO Model, the CPC Initiative, Other Similar Innovation Center Models, or CMS Initiatives
  o Beginning with the 2017 payment adjustment period, to waive application of the VM for groups and solo practitioners, as identified by a TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the Pioneer ACO model, the CPC initiative or other similar CMMI models during the performance period.

- Payment Adjustment Amount
  o Setting the maximum upward adjustment under the quality-tiering methodology for the 2018 VM to:
    - +4.0 times an upward payment adjustment factor (to be determined after the performance period has ended) for groups with 10 or more EPs,
- +2.0 times and adjustment factor for groups with 2 to 9 EPs and physician solo practitioners, and
- +2.0 times an adjustment factor for groups and solo practitioners that consist of nonphysician EPs who are PAs, NPs, CNS, and CRNAs.

  - To set the amount of payment at risk under the 2018 VM to:
    - 4.0 percent for groups with 10 or more EPs,
    - 2 percent for groups with between 2 to 9 EPs and physician solo practitioners, and
    - 2 percent for groups and solo practitioners that consist of nonphysician EPs who are PAs, NPs, CNS, and CRNAs.

- Finality of the VM Upward Payment Adjustment Factor
  - To not recalculate the VM upward payment adjustment factor after it is made public unless there was a significant error in the calculation.

- Performance Period
  - To use 2016 as the performance period for the 2018 VM.

- Quality Measures
  - To align the quality measures and quality reporting mechanisms for the 2018 VM with those available to groups and individuals under the PQRS during the 2016 performance;
    - Beginning with the 2018 VM, to separately benchmark the PQRS electronic clinical quality measures (eCQMs); and
    - Beginning with the 2018 VM, to include the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surveys in the VM for Shared Savings Program ACOs.

- Expansion of the Informal Process to Allow Corrections to the VM
  - Beginning with the 2016 VM, to apply the VM to groups for which the PQRS program removes individual EPs for the program’s unsuccessful participants list.

- Medicare Spending Per Beneficiary (MSPB) Measure
  - Beginning with the 2017 payment adjustment period, to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes.

- Inclusion of Maryland Hospitals stays in Definition of Index Admissions
  - Beginning with the 2018 VM, include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM.

- Average Quality and Average Cost Designations in Certain Circumstances
  - Beginning in the 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a quality composite score that is classified as average if the group or solo practitioner does not have at least one quality measure that meets the minimum number of cases required to be included in the calculation of the quality composite.

- Technical changes to §414.1255 and §414.1235

CMS also seeks comments regarding stratifying cost measure benchmarks by beneficiary risk scores.
a. Group Size

Beginning with the 2016 payment adjustment period, the list of groups and solo practitioners subject to the VM is based on CMS’ query of the PECOS within 10 days of the close of the PQRS group registration process during the applicable performance period. Groups are removed from the PECOS generated list, if based on the analysis of claims, the groups did not have the required number of EPs that submitted claims during the performance period for the applicable CY payment adjustment. Solo practitioners are removed from the PECOS list if, based on the claims analysis, they did not submit claims during the performance period for the applicable CY payment adjustment period. In the 2014 final rule, CMS also finalized that for the 2016 payment adjustment period and subsequent adjustment period, based on the analysis of claims groups will not be added to the PECOS list.

Beginning with the 2016 VM, CMS established different payment adjustment amounts for groups with different numbers of EPs. CMS notes that they have not addressed how to handle scenarios where the size of a TIN based on the PECOS list is not consistent with the size of a TIN based on analysis of claims data. Beginning with the 2016 payment adjustment, CMS proposes the TIN’s size would be determined based on the lower of the number of EPs indicated on the PECOS list or by the analysis of the claims data for purposes of the determining the payment adjustment amount under the VM. Thus, when there is a discrepancy in the group size between PECOS and claims analysis, CMS would apply the payment adjustment to the lower group size and the group would be subject to the lower amount at risk and lower possible upward payment adjustment.

As discussed below, CMS proposes to apply the VM in the 2018 payment adjustment period to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs in groups with two or more EPs and to those who are solo practitioners. CMS proposes:

- To identify TINs that consist of nonphysician EPs as those TINs for which either the PECOS list or the analysis of claims data shows that the TIN consists of nonphysician EPS and no physicians. The VM would only apply to the PAs, NPs, CNSs, and CRNAs who bill under these TINs and not to the other types of nonphysician EPs who may bill under the TIN.
- The VM would not apply to a TIN if either the PECOS list or the analysis of claims data shows that the TIN consists of only nonphysician EPS who are not PAs, NPs, CNSs, and CRNAs.

b. Application of the VM to Nonphysician EPs

With the enactment of MACRA, on or after January 1, 2019, the Merit-based Incentive Payment System (MIPS) and not the VM, will apply to payments for items and services. For payments and items and services furnished in 2019 and 2020, the MIPS will only apply to:

- A physician (as defined in section 1861(r) of the Act);
- A PA, NP, and CNS (as defined in section 1861(aa)(5) of the Act);
- A CRNA (as defined in section 1861(bb)(2) of the Act); and
- A group that includes such professionals.
Beginning with payments for items and services furnished in 2021, the Secretary has the discretion to apply the MIPS to other EPs as defined in section 1848(k)(3)(B) of the Act.

In the 2015 final rule, CMS finalized that beginning with the 2018 payment adjustment period the VM would apply to all types of nonphysician EPs in groups with two or more EPS and to nonphysician EPs who are solo practitioners. However, CMS believes it would no longer be appropriate to apply the VM in 2018 to any nonphysician EP who is not a PA, NP, CNS, or CRNA since payment adjustments under the MIPS would not apply to them until 2021. Thus, CMS proposes to apply the VM in the 2018 payment adjustment period to nonphysicians EPs who are PAs, NPs, CNSs and CRNAs in groups with two or more EPs and to those who are solo practitioners and not to other types of professionals who are nonphysician EPs. CMS proposes to define PAs, NPs and CNSs as those terms are defined in section 1861(aa)(5) of the Act and CRNAs as defined in section 1861(bb)(2) of the Act. The VM would not apply to other types of nonphysician EPs who may bill under a group’s TIN.

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

Category 1
CMS notes that during the 2014 PQRS submission period, they received feedbacks from groups who encountered difficulties reporting through the reporting mechanism they had chosen at the time of the 2014 PQRS GPRO registration. To address these concerns, CMS proposes that for the 2018 VM, Category 1 would include those groups that meet the criteria to avoid the PQRS payment adjustment for 2018 as a group participating in the PQRS GPRO (as proposed in Table 21) and to also include in Category 1, groups that have at least 50 percent of the group’s EPS meet the criteria to avoid the PQRS payment adjustment for 2018 as individuals (as proposed in Table 20). CMS explains that this proposed criteria for groups is different that the policy for the 2017 VM, in that for the 2017 VM CMS only considers whether at least 50 percent of a group’s EPs met the criteria to avoid the PQRS payment adjustment as individuals if the group did not register to participate in a PQRS GPRO. Under CMS’ proposal for the 2018 VM, CMS would consider whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO.

CMS also proposes to similarly revise the criteria for groups to be included in Category 1 for the 2017 payment adjustment, if it is operationally feasible for the CMS systems to utilize data reported through a mechanism other than the one through which a group registered to report under PQRS GPRO. If it is not operationally feasible, then CMS will apply the existing policy for the 2017 VM to consider whether at least 50 percent of a group’s EPs meet the criteria to avoid the PQRS payment adjustment for 2017 as individuals only when the group did not register to report under the PQRS GPRO.

CMS also proposes to include in Category 1 for the 2018 VM those solo practitioners that meet the criteria to avoid the 2018 PQRS payment adjustments as individuals (as proposed in Table 20).
Category 2
CMS proposes that Category 2 would include those groups and solo practitioners that are subject to the 2018 VM and do not meet the criteria for Category 1.

d. Application of the VM to Physicians and Nonphysician Eligible Professionals Who that Participate in ACOs under the Shared Savings Program

Beginning with the 2017 payment adjustment period, CMS will apply the VM to physicians in groups with two or more EPs and to physicians who are solo practitioners that participate in the Shared Savings Program as part of an ACO. Beginning with the 2018 payment adjustment period, apply the same VM nonphysician EPs in groups and nonphysician EPs who are solo practitioners that participate in the ACO under the Shared Savings Program. CMS would classify the group or solo practitioner’s cost composite as “average” and calculate the quality composite based on the quality-tiering methodology using quality data submitted by the ACO for the performance period and apply the same quality composite to all of the groups and solo practitioners, as identified by the TIN, under the ACO.

1. Application of the VM to Groups and Solo Practitioners who Participate in Multiple Shared Savings Program ACOs

Under the Shared Savings Program regulations, an ACO participant TIN upon which beneficiary assignment is dependent may only participate in one Shared Savings ACO. ACO participant TINs that do not bill for primary care services, however, are not required to only participate in one ACO. CMS notes they have not previously addressed how the VM will apply to the small number of TINs that are ACO participants in multiple Shared Savings Program ACOs.

Beginning with the 2017 payment adjustment period, CMS proposes that TINs participating in multiple ACOs in the applicable performance period would receive the quality composite score of the ACO with the highest numerical quality composite score. CMS will only consider the quality data of an ACO that completes quality reporting. For example, TIN A participates in ACO 1 and ACO 2 in the 2015 performance period. ACO 1 fails to complete quality reporting and ACO 2 completes quality reporting. Using ACO 2’s quality data and applying the quality-tiering methodology, TIN A is classified as average quality. Under CMS’ proposal, TIN would receive a neutral VM in 2017 based on a quality composite determined using ACO 2’s quality reporting and a cost composite of average. Additional examples are provided in the proposed rule.

CMS discusses how under the VM, any TIN’s quality composite score must be at least one standard deviation away from and statistically significant different from the mean, for it to be classified as other than average quality. It is possible that including performance data for the ACO with the highest quality composite score in a given TIN’s VM calculation would result in a higher VM adjustment percentage than would inclusion of data from another ACO with a lower quality composite score that is also at
least one standard deviation from the mean. CMS expects this situation is rarely occur and provides the following example:

TIN B participates in ACO 2 and ACO 3 in the 2015 performance period. The quality composite score using ACO 2’s quality data is two standard deviations below the mean but is not statistically below the mean; the quality composite score would be classified as average because it is not statistically below the mean. The quality composite score using ACO 3’s quality data is one and a half standard deviation below the mean and is statistically below the mean; the quality composite score would be classified as low because it is statistically below the mean. Based on the CMS proposal because the quality composite score that is one and a half standard deviations below the mean (ACO 3) is numerically higher than the quality score that is two standard deviations below the mean (ACO 2), TIN B would receive a negative VM is 2017 based on a quality composite determined using ACO’s quality reporting and a cost composite of average.

CMS believes this proposal is appropriate because it is transparent and straightforward. CMS considered other alternatives, including if any of the ACOs in which the TIN participated failed to complete quality reporting, the TIN would be categorized as Category 2 and the option of allowing the TIN to select which ACO it wanted to be associated with for the purposes of the VM. CMS welcomes feedback on these alternatives.

Because they did not make proposals for applying the VM to these TINs prior to the start of the performance period for the 2017 VM, CMS does not believe it would be fair to give ACO participants in multiple Shared Savings Program ACOs the lower of the quality composite score for which they have been eligible.

2. Application of VM to Participant TINs in Shared Savings ACOs that also Include EPs who Participate in Innovation Center Models

CMS is proposing that beginning with the 2018 payment adjustment period, to apply the VM for groups and solo practitioners (as identified by TIN) who participated in a Shared Savings Program ACO during the applicable the performance period, regardless of whether any EPs under the TIN also participated in an Innovation Center model during the performance period. (Note: In the proposed rule, in section III.M.4, this proposal begins with the 2018 payment adjustment but in section III.M.4.d.2 this proposal begins with the 2017 payment adjustment period. Since the performance period for the 2017 payment adjustment has already begun, we are assuming CMS means the 2018 payment adjustment period but this will need clarification from CMS.)

3. Application of VM to Participant TINs in Shared Savings Program ACOs that Do Not Complete Quality Reporting

CMS proposes for the 2018 payment adjustment period, to continue the policy that if the ACO does not successfully report quality data as reported by the Shared Savings Program, all groups and solo practitioners participating in the ACO will be in Category 2 for the VM and will be subject to a downward payment adjustment. CMS notes this
4. **Application of an Additional Upward Payment Adjustment to High Quality Participant TINs in Shared Savings Program ACOs for Treating High-risk Beneficiaries**

For the 2017 payment adjustment period, groups and solo practitioners that are classified as high quality/low cost, high quality/average cost, or average quality/low cost under the quality-tiering methodology will receive an additional upward payment adjustment of +1.0x, if their attributed patient population has an average risk score that is in the top 25 percent of all beneficiary risk scores nationwide.

CMS is proposing a similar policy for high quality participant TINs in Shared Savings Program ACOs. Specifically, beginning with the 2017 payment adjustment period, CMS proposes to apply an additional upward payment adjustment of +1.0x to groups and solo practitioners that participated in high performing Shared Savings Program ACOs that cared for high risk beneficiaries during the performance period. The ACO would need to have an attributed patient population that has an average risk score that is in the top 25 percent of all beneficiary risk scores nationwide as determined by the VM methodology. CMS notes that in this proposal is based on using the ACO’s assigned beneficiary population; the proposal that was not finalized in the 2015 rulemaking cycle was based on using the group or solo practitioner’s attributed beneficiary population.

e. **Application of the VM to Physicians and Nonphysician EPs that Participate in the Pioneer ACO Model, the CPC Initiative, Other Similar Innovation Center Models or CMS Initiatives**

**Pioneer ACO Model and the CPC Initiative**

In the 2015 final rule, CMS finalized that beginning with the 2017 payment adjustment period, the VM would apply to physicians in groups with two or more EPs in which at least one EP 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. CMS also finalized that the cost composite would be average cost and the quality composite would be average quality for the 2017 payment adjustment period.

The majority of commenters were opposed to applying the VM to participants in the Pioneer ACO and CPC Initiative. A few commenters suggested that the application of the VM to Innovation Center initiatives should be waived under section 1115A of the Act. CMS agrees with these commenters and under section 1115A(d)(1) of the Act, is proposing to waive application of the VM as required by section 1848(p) of the Act for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the Pioneer ACO Model or CPC Initiative during the performance period. CMS notes that this proposed policy, as well as the use of the waiver authority under section 1115(A)(d)(1) of the Act for this purpose, will no longer apply in 2019 when the VM is incorporated into the MIPS. CMS believes a waiver is necessary to test
these models because their effectiveness would be impossible to isolate from the confounding variables of quality and cost metrics and contrasting payment incentives under the VM. (For additional details, see the proposed rule.)

CMS notes that they believe that could have previously waived application of the VM for these models for the 2017 payment adjustment period, and are now proposing the waiver would begin with the 2017 payment adjustment. CMS notes that in practice this proposal would not affect a TIN’s payment because the policy to classify a TIN as average cost and average quality would receive a neutral (0 percent) adjustment, and thus payments during 2017 would not increase or decrease as a result of the application of the VM.

The proposed waiver would also affect the payments for items and services billed under the PFS for 2017 and 2018 payment adjustment for the EPs who participate in the Pioneer ACO model and the CPC Initiative during the performance period, as well as the EPs who do not participate in these models but bill under the same TIN as the EPs who do participate.

Similar Innovation Center Models
In the 2015 final rule, CMS finalized criteria to determine if future Innovation Center models or CMS initiatives are “similar” to the Pioneer ACO and CPC Initiative and finalized applying the same VM policies adopted for participants in the Pioneer ACO and CPC Initiative. The criteria are:

- 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 proposes that if the above proposal to waive the application of the VM to the Pioneer ACO and CPC Initiative is finalized, they would also waive application of the VM for Innovation Center models that are determined, based on the above criteria, to be similar models. In the proposed rule, CMS discusses why they consider the Comprehensive ESRD Care Initiative, the Oncology Care Model, and the Next Generation ACO Model are similar models and why a waiver of the VM is necessary.

Application of VM to Similar CMS Initiatives that are not Innovation Center Models
In the 2015 final rule, CMS finalized criteria to determine if future CMS initiatives are “similar” to the Pioneer ACO and CPC Initiative and finalized applying the same VM policies adopted for participants in the Pioneer ACO and CPC Initiative (the criteria are described above). CMS notes that the waiver authority under section 1115A(d)(1) of the Act does not apply to CMS initiatives that are not Innovation Center models. If any
CMS initiatives that are not Innovation Center models would require alternative policies for application of the VM, CMS would address this through future rulemaking.

\( f. \) Payment Adjustment Amount

Section 1848(p)(4)(C) of the Act requires the VM to be implemented in a budget neutral manner.

Because the VM will not be applied to payments for items and services furnished on or after January 1, 2019, CMS proposes to maintain the payment adjustment amounts in 2018 that they finalized for groups with 10 or more EPs. CMS also proposes to maintain the payment adjustments amounts in 2018 for groups with 2 or more EPs and physicians solo practitioners except CMS proposes to apply both the upward and downward adjustment under the quality-tiering methodology to groups with 2 to 9 EPs and physician solo practitioners that are in Category 1.

For 2018, the tables below (copied from the proposed rule) illustrate CMS proposals for the VM payment adjustments.

**TABLE 33: 2018 VM Amounts for the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, and CRNAs in Groups with Ten or More EPs**

<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 +1.0 if reporting PQRS quality measures and average beneficiary risk score is in the top 25th percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment factor.

For 2018, CMS proposes to apply a -4.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs that are in Category 2.

**TABLE 34: 2018 VM Amounts for the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, and CRNAs in Groups with 2 to 9 EPs and Physician 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>-1.0%</td>
<td>+0.0%</td>
<td>+1.0x*</td>
</tr>
<tr>
<td>High Cost</td>
<td>-2.0%</td>
<td>-1.0%</td>
<td>+0.0%</td>
</tr>
</tbody>
</table>

*Groups and solo practitioners eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment.
For 2018, CMS proposes to apply a -2.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with 2 to 9 EPs and physicians solo practitioners that are in Category 2.

**TABLE 35: 2018 VM Amounts for the Quality-Tiering Approach for PAs, NPs, CNSs, and CRNAs in Groups Consisting of Nonphysician EPs and PAs, NPs, CNSs, and CRNAs Who are Solo Practitioners**

<table>
<thead>
<tr>
<th>Cost/Quality</th>
<th>Low Quality</th>
<th>Average Quality</th>
<th>High Quality</th>
</tr>
</thead>
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<tr>
<td>Low Cost</td>
<td>+0.0%</td>
<td>+1.0x*</td>
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</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 PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where ‘x’ represents the upward payment adjustment.

For 2018, CMS proposes to apply a -2.0 percent VM to PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners that are PAs, NPs, CNSs, and CRNAs that are in Category 2.

CMS notes that the estimated funds derived from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 would be available to all groups and solo practitioners eligible for an upward adjustment. Consequently, the upward payment adjustment factor (‘x’ in Tables 33, 34, and 35) would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

**g. Finality of the VM Upward Payment Adjustment Factor**

CMS is proposing that they would not recalculate the upward payment adjustment factor for an applicable payment period after the adjustment factor is made public, unless CMS determines that a significant error was made in the calculation. CMS notes this will provide EPs that are eligible for an upward payment adjustment finality and also minimize the cost of reprocessing claims.

**h. Performance Period**

CMS proposes to use 2016 as the performance period for the VM adjustments that will apply during 2018.
i. Quality Measure

PQRS Reporting Mechanisms
For the VM in 2018, CMS proposes to include all of the PQRS GPRO reporting mechanisms available to groups for the PQRS reporting periods in 2016 and all of the PQRS reporting mechanisms available to EPs for the PQRS reporting periods in 2016. These reporting mechanisms are described in Tables 20 and 21.

PQRS Quality Measures
For the VM in 2018, CMS proposes to continue to use 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 to the extent that a group (or individual EPs in the group, in the case of the “50 percent option”) or solo practitioner submits data on these measures. CMS will continue to use the three outcome measures in the quality measures: (1) composite of rates of potentially preventable hospital admissions for heart failure (HF), chronic obstructive pulmonary disease (COPD) and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections (UTIs), and bacterial pneumonia; and (3) rates of an all-cause hospital readmissions measure.

Benchmarks for eCQMs
The VM program currently utilizes quality of care benchmarks for a given performance year that are calculated as the case-weighted mean of the prior year’s performance rates, inclusive of all available PQRS reporting mechanisms for that measure (claims, registries, EHR, or Web Interface). CMS refers to quality measures reported through the EHRs as “eCQMs”.

CMS has learned from experience in utilizing PQRS measures in the VM, that a given measure may be calculated differently when it is collected through as EHR. The inclusion of all-payer data for the eCQMs differentiate them from their equivalent measures reported through other PQRS reporting mechanisms, which utilize Medicare FFS data. In addition, eCQMs follow a different annual update cycle than do other versions of measures and they might not be consistent with the current version of measures reported through other mechanisms. As a result of these differences, CMS notes that the eCQM version of a measure may differ from the specifications of the all-mechanism benchmark to which it is currently compared. CMS proposed to change the benchmark policy to indicate that eCQMs, as identified by their CMS eMeasure IDs, which are distinct from the CMS/PQRS measure numbers for other reporting mechanisms, will be recognized as distinct measures under the VM. CMS will exclude eCQM measures from the overall benchmark for a given measure and create separate eCQM benchmarks based on the CMS eMeasure ID. CMS proposes for the 2016 performance period, eCQM benchmarks would be calculated based on 2015 performance data.
CAHPS Reporting
CMS notes that the criteria for administration of the CAHPS for a PQRS survey for the 2016 performance period will contain 6 months of data (proposed in Section III.1.5.a of the proposed rule). CMS believes that this 6-month period would be sufficiently reliable to allow a group to have CAHPS for PQRS included in a group’s quality composite score. CMS would require data for each summary survey measure on at least 20 beneficiaries which is the reliability standard for the VM.

Quality Measures for the Shared Savings Program
In the 2015 final rule, CMS finalized a policy to use the ACO GPRO Web Interfaces and the Shared Savings Program ACO all-cause readmission measure to calculate a quality composite score for groups and solo practitioners who participate in an ACO under the Shared Savings Program.

CMS is proposing that beginning with the 2016 performance period and the 2018 payment adjustment period, the ACO CAHPS survey will be required as an additional component of the VM quality composite for TINs participating in the Shared Savings Program. CMS proposes that whichever version of the CAHPS survey the ACO chooses to administer will be included in the TIN’s quality composite for the VM. CMS believes that by the 2016 performance period, they will have sufficient data and experience with calculating these survey measures in the VM, to require the ACO CAHPS measures in conjunction with the GPRO WI measures and the all-cause readmission measure in the calculation of a quality composite score for groups and solo practitioners participating in an ACO.

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

Despite the preclusion of administrative and judicial review, CMS believes an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and established an informal inquiry process at §414.1285.

For the 2015 payment adjustment period, to align with PQRS, CMS expanded the established informal inquiry process and established an initial corrections process that would allow for some limited corrections. CMS notes there is no administrative or judicial review of the determination resulting from this expanded informal inquiry process. For both the 2015 payment adjustment period and future adjustment periods, CMS finalized a policy to adjust a TIN’s quality-tier if they make a correction to a TIN’s quality/and or cost composites because of this correction process. In the 2015 final rule, CMS noted that if the operational infrastructure is not available to allow the recomputation of quality measure data, CMS would continue to classify a TIN as average quality in the event that CMS or a third-party vendor made an error in the calculation of the quality composite. CMS proposes to continue this policy for the 2016 payment and future payment adjustment periods or until such a time the operational infrastructure is in place to allow the recomputation of data.
CMS’ overall approach to the VM is based on participation in the PQRS. CMS notes that the payment adjustment for the VM is applied at the TIN level whereas the PQRS payment adjustment is applied at the TIN/NPI level. Because of this difference, CMS believes a policy is needed to address the circumstance in which a group is initially determined not to have met the criteria to avoid the PQRS payment adjustment and subsequently, through the informal review process, at least 50 percent of its EPs are determined to have met the criteria to avoid the PQRS payment adjustment as individuals. CMS proposes to reclassify a TIN as Category 1 when PQRS determines on informal review that at least 50 percent of the TIN’s EPs meet the criteria for satisfactory reporting of data on PQRS measures as individuals for the relevant CT payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS QCDR for the relevant CY PQRS payment adjustment. CMS notes that if the group was initially classified as Category 2, they do not expect to have data for calculating their quality composite and they would be classified as average quality. If the data is available in a timely manner, then CMS would recalculate the quality measure.

**k. Minimum Episode Count for the Medicare Spending Per Beneficiary (MSPB) Measure**

In the 2014 final rule, CMS finalized inclusion of the MSPB measure in the cost composite beginning with the 2016 VM, with a 2014 performance period. CMS finalized a minimum of 20 MSPB episodes of inclusion of the MSPB in a TIN’s cost composite; the nonspecialty-adjusted version of the measure using 2011 data had high reliability with a 20 episode minimum. CMS notes they refined the methodology to account for the changes in measure specifications and the results for the specialty-adjusted measure were more reliable at higher episode minimums. CMS states that by using a more appropriate methodology for calculating reliability, they found that the specialty-adjusted measure does not have moderate or high reliability with a 20 episode minimum for many groups. Table 36 shows the reliability of the measures for different group sizes as the case minimum increases.

Beginning with the 2017 payment adjustment period (2015 performance period), CMS proposes to increase the episode minimum to 100 episodes. CMS notes this would reduce the number of group and solo practitioners included in the MSPB calculation in the cost calculation (from 29,190 to 8,543 based on 2013 data).

CMS notes they considered increasing the episode minimum to 75 instead of 100; this would allow inclusion of the MSPB measure in the cost composite for a larger number of groups. CMS believes, however, that the reliability for solo practitioners with a minimum of 100 episodes was preferable to the reliability when using a 75 episode minimum. CMS welcomes comments on this alternative as well as other potential minimum case thresholds for this measure.
CMS also considered revising the case minimum for the MSPB measure beginning with the 2016 payment adjustment period (2014 performance period), but did not propose this policy because this PFS rule will be finalized after the 2014 QRURs with the 2016 VM payment adjustment information are released. CMS notes that using an episode minimum of 20 for the 2016 VM, the MSPB has moderate reliability for the majority of groups that will be subject to the VM in 2016 (60.9 percent of groups with 10-24 EPs, 66.5 percent of groups with 25-99 EPs, and 89.7 percent of groups with 100 or more EPs).

l. Inclusion of Maryland Hospital Stays in Definition of Index Admissions

CMS uses the MSPB measure as specified for the Hospital Inpatient Quality Reporting and Hospital Value Based Purchasing (VBP) Program with an exception to changes to the attribution methodology. This MSPB measure does not include hospitalizations at Maryland hospitals as an index admission that would trigger an episode because Maryland hospitals are not paid under the IPPS and do not participate in the Hospital VBP Program. Because of this exclusion, groups and solo practitioners in Maryland would not have the MSPB measure included in their cost composite under the VM.

Beginning with the 2018 VM, CMS proposes to change the definition of index admissions used for the MSPB used in the VM program to include inpatient hospitalizations at Maryland hospitals. CMS would continue to use their standardized methodology currently used in the calculation of the MSPB measure.

m. Average Quality and Average Cost Designations in Certain Circumstances

Currently, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the VM. Based on the proposals discussed below, CMS proposes to specify in §414.1265(b)(1) that this policy is applicable only to the 2015 payment adjustment.

Beginning with the 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a cost composite score that is average under quality-tiering if they did not have at least one cost measure with at least 20 cases. Beginning with the 2017 payment adjustment period, CMS is proposing to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes. Thus, CMS proposes to revise §414.1265(b) to indicate that a group or solo practitioner subject to the VM would receive a composite score that is classified as average under the quality-tiering methodology if they do not have at least one cost measure that meets the minimum number of cases required for the measure to be included in the calculation of the cost composite (§414.1265).

Beginning with the 2017 payment adjustment period, the all-cause hospital readmission measure must have 200 or more cases. CMS proposes that beginning with the 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a quality composite score that is classified as average under the quality-tiering methodology if they do not have at least one quality measure that meets the minimum
number of cases required for the measure to be include in the calculation of the quality composite (§414.1265).

n. Technical Changes to the “Benchmarks for cost measures” Section of Regulation Text

As described in the proposed rule, CMS is proposing to make technical changes to regulations describing specialty adjustment of cost measures and benchmarks for cost measures. They are not proposing any methodological changes.

o. Discussion of Stratification of Cost Measure Benchmarks by Beneficiary Risk Score

CMS discusses concerns that stakeholders have raised that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measure for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries. Commenters stated that groups working exclusively in post-acute and long-term care settings would be unable to perform well on cost measures under the current methodology. CMS notes that high costs within these settings present ‘a unique opportunity for these providers to improve performance on cost and quality measures’ and are continuing to monitor these groups and solo practitioners’ performance under the VM and consider potential risk adjustment refinements.

CMS is considering to stratify the cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with a similar risk profile. CMS believes that this would provide an opportunity to gain efficiencies in care and lower costs within a given grouping (e.g. a quartile or decile) while beneficiary severity of illness and practice characteristics may be more fully recognized at a smaller, and less-heterogeneous, attributed beneficiary level. CMS seeks feedback on this potential approach and other approaches.

p. Regulatory Impact Analysis

CMS notes that the proposed changes in the VM discussed in this proposed rule would not impact the 2016 physician payments under the PFS. CMS has not completed the analysis of the VM in 2016 on physicians in groups with 10 or more EPS based on their performance in 2014. They will provide the actual number of groups of physicians subject to the VM in the final rule.

5. Physician Feedback Program

CMS plans in late fall 2015 to disseminate QRURs based on 2014 data to all solo practitioner EPs and all groups of EPs, as identified by TIN, including nonphysician EP solo practitioners and groups comprised of nonphysician EPS. CMS also plans to make the 2014 QRURs available to Shared Savings Program ACO participant TINs and groups that include one or more EPs who participated in a Pioneer ACO or CPC
Initiative. CMS notes these reports will contain performance on the quality and cost measures used to score the cost and quality composites for the VM.

In spring 2015, in response to stakeholders feedback to provide more timely information, CMS provided the 2014 Mid-Year QRUR (MYQRUR). The 2014 MYQRUR reports were provided to physician solo practitioners and groups of physicians who billed for Medicare-covered services under a single TIN over the period of July 1, 2013 through June 30, 2014. CMS notes these reports are for informational purposes and do not estimate performance for the calculation of the VM. Beginning in Spring 2016, CMS intends to expand the distribution of MYQRURs to nonphysician EPs, solo practitioners and groups composed of nonphysician EPs. CMS invites comments on which aspect of the QRURs have been most helpful and how they can improve performance reports.

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

In the summer of 2014, CMS distributed the Supplemental QRUR, episodes of care based on 2012 data, to groups with 100 or more EPs; this provided information on 20 episode subtypes and 6 clinical episode-based measures. This fall 2015, CMS expects to provide the 2014 Supplemental QRURs to all groups and solo practitioners who bill for Medicare-covered services under a single TIN in 2014 and have sufficient data to calculate at least one episode measure. CMS notes that the supplemental QRURS will likely include the 6 episode-based measures used in the 2012 reports (kidney/urinary tract infection, cellulitis, gastrointestinal hemorrhage, hip replacement, knee replacement/revision, and lumbar spine fusion/refusion) in addition to other episode-based payment measures.

N. Physician Self-Referral Updates

The physician self-referral statute (section 1877 of the Act) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies. CMS discusses the history of the Act and of its implementation, including changes made under the ACA and more recently the MACRA. CMS discusses the Medicare self-referral disclosure protocol (SRDP) for providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute, in part because the agency has identified areas of confusion or concern among stakeholders with respect to the specific requirements of the various exceptions to the statute.
CMS proposes to update its regulations to accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance. It also proposes two new exceptions: (1) Assistance to employ a nonphysician practitioner, and (2) Timeshare arrangements.

1. Recruitment and Retention

a. Assistance to Employ a Nonphysician Practitioner (§411.357(x))

CMS proposes a new limited exception for hospitals, FQHCs, and RHCs to provide remuneration to a physician to assist with the employment of a nonphysician practitioner (NPP) in a geographic area served by the hospital, FQHC, or RHC (hereinafter referred to collectively as “hospital”). This proposed exception would protect both direct compensation arrangements between the hospital and an individual physician and indirect compensation arrangements between the hospital and a physician “standing in the shoes” of a physician organization to which the hospital provided remuneration. The new exception is intended to recognize the increased role NPPs play in meeting primary care needs and in improving patient outcomes and reducing costs, and to expand access to primary care services, especially in rural areas. CMS imposes several conditions for the remuneration to qualify for the proposed new exception.

The NPP would have to be a bona fide employee, and the purpose of the employment would be to provide primary care services to patients of the physician practice. CMS seeks comment on whether the exception should also apply to NPPs who are independent contractors.

NPPs would be limited to nurse practitioners, physician assistants, clinic nurse specialists, and certified nurse midwives; certified registered nurse anesthetists would be excluded. CMS seeks comment on whether to expand the types of NPPs for the new exception.

The exception would apply for NPPs who furnish only primary care services (meaning general family practice, general internal medicine, pediatrics, geriatrics and obstetrics and gynecology); specialty care services (e.g., cardiology or surgical services) would not be protected. CMS seeks comment on whether more or fewer types of primary care services should be included and whether there is a compelling need for NPPs who furnish non-primary care services.

CMS proposes two alternative standards for the minimum amount of primary care services the NPP must furnish to patients of the physician practice under the proposed exception: 90 percent of patient care services or 75 percent of patient care services (known as the “substantially all” standard under regulations). CMS seeks comment on the appropriate standard.

CMS proposes a cap on the amount and duration of the hospital remuneration to the physician under the proposed exception. The cap would be the lower of (1) 50 percent
of the actual salary, signing bonus and benefits paid to the NPP, or (2) an amount calculated by subtracting the receipts attributable to services furnished by the NPP from the actual salary, signing bonus, and benefits paid to the NPP by the physician. CMS does not believe it is necessary to require that the NPP’s salary, signing bonus and benefits be set in advance. CMS does note however that the employing physician may not impose unreasonable practice restrictions on the NPP’s ability to provide patient care services in the geographic area served by the hospital. The duration of the remuneration arrangement would be limited to the first two consecutive years of NPP employment by the physician. CMS seeks comment on the proposed caps.

CMS also proposes similar requirements to protect against program or patient abuse as apply to many other exceptions, including that the remuneration arrangement be in writing; be signed by the parties involved; and not be conditioned on the physician’s or NPP’s referral of patients to the hospital. The remuneration may not be determined in a manner that takes into account the volume or value of any actual or anticipated referrals or other business generated between the parties (i.e., business generated by the referring physician or NPP). CMS proposes to define the term “referral” as it relates to an NPP as a request by the NPP that includes the provision of any Medicare DHS, the establishment of any plan of care by the NPP that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS. However, the term referral would not include any DHS personally performed or provided by the NPP. The arrangement may not violate the federal anti-kickback statute or any federal or state law on billing or claims submission. Records of the remuneration arrangement would have to be retained for at least six years. CMS seeks comment on these requirements.

To address concerns about rotating or cycling NPPs through multiple physician practices in the geographic area served by the hospital, CMS proposes to preclude remuneration arrangements to physicians under this exception where (1) the NPP practiced in that geographic area within 3 years before being employed by the physician in such area; or (2) the NPP was employed by a physician with a medical office in the geographic area served by the hospital within 3 years of being employed by the physician (even if the NPP did not provide patient care services in that office). CMS seeks comment on the 3-year timeframe.

CMS also seeks comment on possible additional safeguards, including a limit on the number of times a hospital may provide assistance to the same physician; whether the agency should require a documented need for additional primary care services in the area, and whether this exception would be helpful to FQHCs and RHCs.

b. Geographic Area Served by FQHCs and RHCs

Section 1877(e)(5) of the Act contains an exception for remuneration offered by a hospital to a physician to relocate his or her practice to the geographic area served by

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7 Benefits would only include health insurance, paid leave, and other routine non-cash benefits offered to other similarly situated employees of the physician practice.
the hospital (i.e., the physician recruitment exception). The definition of “geographic area served by the hospital” is determined using a percentage of the hospital’s inpatients (75 percent, or 90 percent in the case of rural hospitals) and contiguous (or in some cases noncontiguous) zip codes. Since FQHCs and RHCs by definition only treat outpatients or ambulatory patients, the physician recruitment exception is not available.

CMS proposes a definition of “geographic area served by the hospital” for use by FQHCs and RHCs under two possible alternative approaches:

1. The area composed of the lowest number of contiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, determined on an encounter basis.
2. The area composed of the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, determined on an encounter basis.

Under the first alternative, CMS proposes procedures in the case where the FQHC or RHC cannot meet the contiguous zip code requirement. It proposes adding noncontiguous zip codes (beginning with the noncontiguous zip code where the highest percentage of its patients reside and continuing to add noncontiguous zip codes in decreasing order of percentage of patients) and also allows the inclusion of zip codes where no patients reside as long as those zip codes are surrounded by zip codes in the geographic area from which it draws at least 90 percent of patients.

Under the second alternative, the 90 percent threshold would be determined beginning with the zip code in which the highest percentage of patients reside and continuing to add zip codes in decreasing order of percentage of patients. **CMS seeks comments of both alternatives as well as on whether patient encounters is the appropriate measure for the geographic area.**

*Conforming Terminology:* “Takes Into Account.” The language of the regulations uses different terminology to modify the volume or value of referrals standard, including “takes into account,” “based on,” and “without regard to” which CMS is concerned opens the door to different interpretations of what the standard requires under different compensation arrangement exceptions. CMS believes there is no substantive difference in the legal meaning between the various phrases and proposes to use the phrase “takes into account” to modify the volume or value of referrals standard at §§411.357(e), (m), (r), and (s).

*Retention Payments in Underserved Areas.* CMS proposes a technical amendment to the language of its regulations for the retention exception (under §411.357(t)) to reflect the intent it set forth in the preamble of its final rule (72 FR 51066). Specifically, CMS proposes to revise §411.357(t)(2)(iv) to provide that retention payments “…may not exceed the lower of: (1) an amount equal to 25 percent of the physician’s current annual income (averaged over the previous 24 months)…” instead of the current regulations
which read “an amount equal to 25 percent of the physician’s current income (measured over no more than a 24-month period)…”.

2. Reducing Burden and Improving Clarity Regarding the Writing, Term, and Holdover Provisions in Certain Exceptions and other Regulations

**Writing Requirements.** Through the SDRP, CMS has learned that uncertainty exists on the writing requirements for the leasing and other compensation exceptions, especially whether an arrangement must be reduced to a single formal written contract. CMS responds that lease arrangements must sufficiently document in writing the facts and circumstances to verify compliance, but there is no requirement that the arrangement be documented in a single formal contract. CMS proposes to substitute the term “lease arrangement” in various places in the regulations for the term “agreement” or “lease agreement” to emphasize that the rules do not require a particular type of writing, such as a formal contract; it also proposes to substitute the term “arrangement” for the term “contract” in various places in the regulations.

**Term Requirements.** Stakeholders have asked whether the term of a rental or personal service arrangement (under §§411.357(a), (b) and (d)) must be set forth in writing. CMS clarifies that a collection of documents that evidences the course of conduct between the parties can establish that an arrangement lasted for the required term; however, it is not necessary to have a written contract with a formalized “term” provision to satisfy the regulations.

**Holdover Arrangements.**

Under certain current exceptions (§§411.357(a), (b) and (d)) for rental and personal service arrangements, holdover arrangements are permitted for up to 6 months if (1) the underlying arrangement lasted one year, (2) the holdover arrangement meets the requirements of the exception, and (3) the holdover arrangement continues under the same terms and conditions. CMS proposes to permit indefinite holdover arrangements or in the alternative holdover arrangements of a specified period of time greater than 6 months (e.g., 1 year or more) provided that additional safeguards are met. CMS also proposes to revise the exception for fair market value compensation at §411.357(l)(2) to permit renewals of arrangements of any length of time.

In making this proposal, CMS reconsiders its earlier position on this issue but includes safeguards to protect against (1) frequent renegotiation of short term arrangements based on physician referrals, and (2) compensation or rental charges that become inconsistent with fair market value over time. To prevent frequent renegotiation, CMS proposes that the holdover must continue on the same terms and conditions as the original arrangement—any changes to those terms would be considered a new arrangement subject to the 1-year minimum term requirements. To ensure the holdover is consistent with or does not exceed fair market value, the holdover arrangement must satisfy all elements of the applicable exception. CMS notes that the requirement that the arrangement be set out in writing continues to apply during the holdover. CMS
would apply these requirements under either alternative described in the preceding paragraph but seeks comments on what additional safeguards would be necessary to ensure holdovers of longer than 6 months do not pose a risk of program or patient abuse.

As noted above, CMS also proposes to amend the regulations at §411.357(l)(2) to permit arrangements of any timeframe to be renewed any number of times, but seeks comments on whether the regulatory change would be necessary in light of those earlier proposals.

3. Definitions

CMS proposes the following revisions to the definitions of key terms in its regulations to ensure clarity and proper application of its policies.

a. Remuneration (§411.351)
Under current law, certain types of remuneration do not constitute a compensation arrangement subject to the referral and billing limitations of the physician self-referral statute, including the provision of items, devices, or supplies that are “used solely” to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. CMS is concerned about the possible interpretation of the phrase “used solely” where the provision of the item etc., can be only be used for one (and not more than one) of the six listed purposes; CMS proposes to clarify the language to make it clear that the item must be used solely for one or more of the six listed purposes.

The second issue related to the definition of remuneration arises because of the Third Circuit Court of Appeals decision in United States ex rel. Kosenske v. Carlisle HMA where the court held that a physician’s use of a hospital’s resources (e.g., examination room, nursing personnel, etc.) when treating hospital patients constitutes remuneration even when the hospital bills for the resources and services it supplies and the physician bills for his or her professional fees only. CMS disagrees that this “split bill arrangement” constitutes remuneration under section 1877. However, CMS notes that where a physician or DHS entity bills a non-Medicare payor globally for both the hospital resources and services as well as the physician’s services, the global billing arrangement involves remuneration.

b. Compensation Arrangements – “Stand in the Shoes” (§411.354(c))
Under previous rulemaking, CMS treats all physicians with ownership or investment interests in physician organizations as well as physicians who voluntarily stand in the shoes of those organizations as “standing in the shoes” of their organizations for purposes of direct and indirect compensation arrangements; the exception to this rule is for physicians with only “titular” ownership or investment interests in those physician organizations. In its October 2008 rulemaking, CMS intended to clarify that each physician standing in the shoes of the physician organization was considered a “party” to an arrangement between the physician organization and a DHS entity.

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8 See section 1877(h)(1)(C)(ii) of the Act and regulations at §411.351.
queried whether this meant that when applying the exceptions in §411.355 and §411.357 (to determine whether compensation takes into account the volume or value of referrals or other business generated between the “parties”) the only “parties” to consider are the physicians with ownership or investment interests in their physician organizations.

CMS clarifies that for purposes of the signature requirement, only physicians who stand in the shoes of their physician organization are considered parties to an arrangement; employees and independent contractors would not be parties unless they voluntarily stand in the shoes of the physician organization. However, for all other purposes of the compensation arrangement requirements (i.e., other than the signature requirement) all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity.

c. Locum Tenens Physicians (§411.351)
CMS has continuously defined a locum tenens physician as one who substitutes (i.e., “stands in the shoes”) for a physician in exigent circumstances; this definition is applicable to both group practices and other physicians. CMS proposes to strike the phrase “stand in the shoes” from this definition because the agency believes that the definition is clear without it and that the stand in the shoes provisions specific to compensation arrangements are separate and distinct from the definition of a locum tenens physician.

4. Exception for Ownership of Publicly Traded Securities

For purposes of the exception for ownership in certain publicly traded securities and mutual funds, CMS proposes to strike out-of-date references in its regulations to “securities that are traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD).” CMS believes that electronic stocks markets such as the NASDAQ and the Financial Industry Regulatory Authority (FINRA) for over-the-counter (OTC) securities are modern day equivalents and proposes to include electronic securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

For securities to be included in the scope of this proposed revised exception, trades must be standardized and publicly transparent. Electronic stock markets or OTC quotation systems that trade unlisted stocks, that involve decentralized dealer networks, or that do not publish quotations on a daily basis would be excluded from this exception. CMS seeks comment on whether fewer, different or additional restrictions are needed to protect against program and patient abuse.

5. New Exception for Timeshare Arrangements

Stakeholders have raised the issue of timeshare arrangements for physicians who do not require or who are not interested in traditional office space lease arrangements. Under a timeshare arrangement, a hospital or local physician practice may ask a specialist from a
neighboring community to provide specialty services in a space (i.e., medical office suite that is fully furnished and operational) owned by the hospital or practice on a limited or as-needed basis. CMS also notes the legal distinction between a license and a lease where a license does not confer ownership or control over the premises while a lease does. Because timeshare arrangements are currently analyzed under the exception for rental of office space, they fail to satisfy the requirements of that exception generally because a license does not provide for exclusive use of the premises and the term may be less than one year.

CMS proposes a new exception at §411.357(y) to protect timeshare arrangements that meet the following requirements:

1. The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies and services covered by the arrangement;
2. The arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor’s premises, equipment, personnel, items, supplies, or services;
3. The licensed premises, equipment, personnel, items, supplies, and services are used predominantly to furnish evaluation and management services to patients of the licensee;
4. The equipment covered by the arrangement, if any:
   a. is located in the office suite where the physician performs evaluation and management services,
   b. is used only to furnish DHS that is incidental to the physician’s evaluation and management services and furnished at the time of such evaluation and management services, and
   c. is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests);
5. The arrangement is not conditioned on the licensee’s referral of patients to the licensor;
6. The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties;
7. The arrangement would be commercially reasonable even if no referrals were made between the parties; and
8. The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any federal or state law or regulation governing billing or claims submission.

The exception would only apply to licensors who are hospitals or physician organizations; no other type of DHS entity would be protected. Additionally, no protection would be afforded a hospital or physician organization that sought to be the licensee under a timeshare arrangement with a physician licensor. **CMS seeks comment on whether the scope of the exception is sufficiently broad to improve beneficiary access to care (especially in rural areas); whether there is a compelling need to permit other DHS entities to qualify as licensors; and whether the**
exception should apply where the licensor is a physician who is the source of DHS referrals to the licensee.

With respect to the requirement that the premises, equipment, personnel, items, supplies, and services are used predominantly to furnish evaluation and management services to patients of the licensee, CMS seeks comment on whether predominant use is an appropriate standard, if so how to define it, and whether another standard, such as “substantially all of the services” would be more appropriate.

CMS also seeks comment on whether the equipment location requirement under 4 above should be expanded to the same building as the licensed suite or even an off-site location, and whether it should prohibit the license of equipment absent a corresponding license of office space.

CMS proposes to limit compensation methodologies; for example, per unit-of-service and percentage compensation methodologies (e.g., number of patients seen or amount of revenue raised) would be prohibited. CMS seeks comment on whether the proposed compensation methodology limitations are necessary and whether timeshare arrangements would pose a risk to program or patient abuse absent these limitations.

Finally, CMS notes the proposed new exception would not be available to protect part-time exclusive use office space lease arrangements.

6. Temporary Noncompliance with Signature Requirements

Current rules regarding a temporary failure to comply with a signature requirement for various compensation arrangement exceptions provide for a period to correct the noncompliance as follows:

- 90 days in the case of a signature noncompliance that is inadvertent; and
- 30 days in the case of a signature noncompliance that is not inadvertent.

CMS proposes to apply a uniform deadline of 90 days to correct the signature noncompliance without regard to whether or not the noncompliance is inadvertent. CMS emphasizes that this applies only to the signature requirement of the exceptions involved and notes that an entity may only use this provision once every 3 years with respect to the same referring physician.

7. Physician-Owned Hospitals

The ACA imposed additional restrictions on physician ownership and investment in hospitals (hereinafter referred to as physician-owned hospitals), including disclosure on any public website of the physician-owned hospital and in public advertising for the hospital, a provider agreement in effect as of the end of 2010, and a restriction on any
increase in the percentage of ownership or investment interests in the hospital as of March 23, 2010.

\( a. \text{ Public Website and Public Advertising Disclosure (§411.362(b)(3)(ii)(C))} \)

Stakeholders requested guidance to clarify the following:
- The terms “public website for the hospital” and “public advertising for the hospital;”
- The range of statements that constitute sufficient disclosure; and
- The period of noncompliance for failure to disclose.

For purposes of public website disclosure, CMS proposes to list the following as examples of what does not constitute a public website: social media websites and social media communications used to develop social and professional contacts, electronic patient payment portals, electronic patient care portals, and electronic health information exchanges. CMS notes this proposed list is non-exhaustive; it focuses on availability of relevant information to the general public and whether the information on the website in question is of the type one would expect to find on the hospital’s main website (e.g., history, leadership, governance, list of staff physicians, etc.). CMS seeks comment on whether its proposed examples are appropriate and whether it should instead provide an inclusive definition of what is included in the definition of public website.

For purposes of public advertising disclosure, CMS proposes to define public advertising for physician-owned hospitals as any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital. The proposed definition would exclude communication made to recruit hospital staff (or other similar human resources activities), public service announcements issued by the hospital, and community outreach issued by the hospital. Again, CMS notes this proposed list of exclusions is non-exhaustive and seeks comment on its proposal. CMS clarifies that the determination of whether the public communication is advertising is based on an analysis of the facts and circumstances, and CMS clarifies that it is those facts and circumstances rather than the medium of communication (e.g., billboards or print, radio or television advertising) that determines whether the communication is public advertising.

For purposes of statements that constitute sufficient disclosure of physician ownership or interest, CMS proposes to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is sufficient (e.g., “this hospital is owned or invested in by physicians,” “this hospital is partially owned or invested in by physicians,” “founded by physicians,” “managed by physicians,” “operated by physicians,” or “part of a health network that includes physician-owned hospitals”). CMS declines to specify the location on the website or font size for the disclosure statements.

For purposes of the period of noncompliance for failure to disclose, with respect to the website disclosure requirement, CMS clarifies that the period is the one during which
the physician-owned hospital failed to satisfy the requirement and notes that the earliest possible date of noncompliance is September 23, 2011. For the public advertising disclosure requirement, the period of noncompliance would be the duration of the applicable advertisement’s predetermined initial circulation (unless the hospital amends the advertisement to meet the requirement at an earlier date). CMS notes that if a physician-owned hospital discovers it failed to meet the disclosure requirements, it should report any associated overpayments through the SDRP. CMS seeks comment on possible additional guidance.

b. Determining the Bona Fide Investment Level (§411.362(b)(4)(i))

In the proposed rule, CMS refers to the percentage of ownership or investment interests held by physicians in a hospital as the “bona fide investment level” and the percentage as of March 23, 2010 as the “baseline bona fide investment level.” CMS reports that stakeholders believe that Congress did not intend to limit the definition of physician owner or investor for these levels to referring physicians, and that CMS’s decision to do so frustrated the purpose of the deadlines to establish physician ownership or investments set forth in statute.

CMS agrees and proposes to revise its policies to include direct and indirect ownership and investment interests of physicians (as defined in section 1861(r) of the Act) in both baseline bona fide investment and bona fide investment levels, regardless of whether the physician refers patients to the hospital. Additionally, the direct and indirect ownership and investment interests of an individual who no longer practices medicine would be counted if he or she satisfies the definition of physician. CMS proposes to establish a definition of ownership and investment interest only for purposes of §411.362 that such an interest exists “if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an indirect ownership or investment interest in a hospital exists if: (1) between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.” CMS proposes that such an interest exists “…even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of ownership or investment interest that forms the links in the chain.”

CMS seeks comment on its proposal and also seeks comment on a possible alternative where it would strike references to “referring physician” throughout §411.362. CMS notes that if it finalizes one or more of these proposals for investment levels, a physician-owned hospital may have revised bone fide investment levels that exceed the baseline levels. Thus, it proposes to delay the effective date of any new regulation on this issue until physician-owned hospitals would have time to comply with
the new policy; CMS seeks comment on what would constitute an appropriate delay in the effective date.

Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

Many of the exceptions under the physician self-referral statute for compensation arrangements include a condition that compensation paid under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; CMS refers to these as the “volume or value” and the “other business generated” standards. The underlying policy rationale for these standards and their application is that compensation should be at fair market value for the work or service performed or the equipment or office space leased—it should not be inflated to compensate for the physician’s ability to generate other revenue (see 66 FR 877).

Since the enactment of the physician self-referral statute and the implementation at the regulatory level of the volume or value and other business generated standards, there have been changes in the delivery of health care and payment systems both within the Medicare and Medicaid programs as well as for non-federal payors and patients. Some examples of these changes include the Medicare hospital value-based purchasing (VBP) program (where participation is mandatory), CMMI voluntary demonstration programs such as the bundled payment for care improvement (BPCI) initiatives and Pioneer ACOs as well as the Nursing Home VBP Demonstration and the Community-based Care Transitions Program, the voluntary Medicare Shared Savings Program (MSSP), and similar programs in the commercial sector. All these programs include performance incentives that are tied to measurable improvements in quality outcomes and tied to managing the total cost of care.

The evolution in care delivery models presents challenges for providers of services and suppliers with respect to the physician self-referral statute. Stakeholders argue that structuring incentive compensation and other payments under the delivery reform models can be challenging, even in the case of hospital-employed physicians. Absent waivers authorized under statute (such as those for some CMMI demonstrations and the MSSP), the physician self-referral statute prohibits the financial relationships required for clinical and financial integration for successful reform models, both under federal and non-federal payors. Performance-based or incentive compensation models are particularly problematic. MACRA requires one report to Congress on fraud under Medicare alternative payment models (APM report) and another on options to permit gainsharing arrangements that would otherwise be subject to civil money penalties under section 1128(A)(b) of the Act, specifically under paragraphs (1) and (2) of that section. To better inform those reports, CMS solicits comment on the impact of the physician self-referral statute on health care delivery and payment reform, including perceived barriers to clinical and financial integration and the volume or value and other business generated standards.
CMS also raises the following issues for comment:

- On the issue of barriers to or limitations on achieving clinical and financial integration, are the barriers or limitations more pronounced for hospitals than for other providers or suppliers because all Medicare revenue is from DHS (and, thus, any compensation might be considered to take into account the volume or value of referrals or other business generated by the physician to whom it is paid)?
- Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?
- Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted; what conditions should be imposed to protect against program or patient abuse; and whether a new exception should be structured to protect services (similar to the in-office ancillary services exception)?
- Is legislation required to establish exceptions to support alternative payment models?
- Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?
- Is there need for new exceptions to the physician self-referral law to support shared savings or “gainsharing” arrangements? If so, what types of financial relationships should be excepted; what conditions should be imposed to address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care?
- Is legislation necessary to establish exceptions to support shared savings or “gainsharing” arrangements?
- Should certain entities, such as those considered to provide high-value care to beneficiaries, be permitted to compensate physicians in ways that other entities may not? If so, what conditions should be imposed to protect against program and patient abuse? How should “high-value care” or “high-value entity” be defined?
- Could existing exceptions, such as the exception at §411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and payment model sponsored by a non-federal payor?
- Have litigation and judicial rulings on compensation methodologies, fair market value, or commercial reasonableness generated a need for additional guidance from CMS, especially in the context of delivery system reform?
- Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at §411.357(p) for indirect compensation arrangements?
- Given the changing incentives for health care providers under delivery system reform, should CMS deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should CMS impose? Should this be applied only to certain types of entities furnishing DHS, such as hospitals that provide high value care to our beneficiaries?
O. Private Contracting / Opt-out

Under certain conditions, a physician or practitioner may opt out of participation under the Medicare program to furnish a Medicare beneficiary through private contracts those items and services that would otherwise be paid for under the Medicare program. Before the enactment of section 106(a) of MACRA, a physician or practitioner who sought to opt of Medicare could do so for a 2-year period by filing an opt-out affidavit; those who wished to renew their opt-out status at the end of the two-year period had to file another opt-out affidavit for the succeeding two-year period.

MACRA section 106(a) requires that out-out affidavits filed on or after June 16, 2015, renew automatically; thus there is no need for the filing of a renewal affidavit. A physician or practitioner who does not want their opt-out status to automatically renew may cancel the automatic extension by notifying CMS at least 30 days before the start of the next two-year period.

CMS proposes to revise the regulations to carry out the statutory changes, including the following:

- §405.400 (Definition of opt-out period) and §405.405 (General rules). Automatic renewal of opt-out status unless the physician or practitioner opts out pursuant to §405.445.

- §405.445(a) (Properly cancel opt-out and early termination of opt-out). A physician or practitioner who wants to cancel opt out status must submit written notice of that fact to each Medicare contractor to which claims would otherwise be submitted not later than 30 days before the end of the current 2-year opt-out period. The proposed rule also provides for the following requirement: “[The physician or practitioner must] Notify all Medicare contractors, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the initial 2-year period.”

- §405.450(a) (Appeals). A CMS determination that a physician or practitioner has failed to properly cancel opt out is an initial determination for purposes of appeals. It would be added to the existing list of requirements for opting out of Medicare with respect to which failure to satisfy results in a determination for purposes of an appeal.

IV. Regulatory Impact Analysis

A. RVU Impacts

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

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2015 with proposed payment rates for 2016 using 2014 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 annual update to the PFS conversation factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 through 2025. The CF for 2016 is $36.1096 based upon a 0.5 percent update factor specified under MACRA and a budget neutrality adjustment of 0.9999 (2015 conversion factor of $35.9335*1.005*0.9999). CMS estimates the 2016 anesthesia conversion factor to be $22.6296, which reflects the 0.9999 budget neutrality adjustment, a 0.99602 anesthesia fee schedule adjustment practice expense and malpractice adjustment, and the 0.5 percent update specified under MACRA.

CMS notes that that Section 220(d) of PAMA added a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. CMS further explains that because 2016 represents a transition year in its new process of proposing values for new, revised and misvalued codes in the proposed rule, rather than establishing them as interim final in the final rule with comment period, it will not be able to calculate a realistic estimate of the target amount at the time the proposed rule is published. Thus, CMS did not incorporate the impact of the target into the calculation of the proposed conversion factor. CMS estimates, however, the net reduction in expenditures will be 0.25 percent as a result of proposed adjustments to the relative value established for misvalued codes in this proposed rule, not including interim final changes that will be established in the 2016 PFS final rule.

Table 45 (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).

2016 PFS Impact Discussion
The most widespread specialty impacts of the RVU changes are generally related to two major factors:

1. Changes to RVUs for specific services resulting from the Misvalued Code Initiatives, including the establishment of RVUs for new and revised codes. Several specialties, including radiation therapy centers, radiation oncology, and gastroenterology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and the inputs used to develop RVUs for the codes that describe particular services. Other specialties, including pathology and
independent laboratories, will experience significant increases to payments for similar reasons.

2. Technical improvement that refines the MP RVU methodology. CMS estimates that this will result in in small negative impacts to the portion of PFS payments attributable to malpractice for gastroenterology, colon and rectal surgery, and neurosurgery.

Column F of Table 45 shows the estimated 2016 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. These impacts range from an increase of 9 percent for independent laboratory and an increase of 8 percent for pathology to a decrease of 3 percent for radiation oncology, a decrease of 5 percent for gastroenterology, and a decrease of 9 percent for radiation therapy centers.

Table 46 (Impact of Proposed Rule on CY 2016 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the proposed changes. CMS shows the change in both facility rates and nonfacility rates for these codes.

**TABLE 45: 2016 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty**

<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>
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<tr>
<td>TOTAL</td>
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<td>0%</td>
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<td>ALLERGY/IMMUNOLOGY</td>
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<td>ANESTHESIOLOGY</td>
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<td>AUDIOLOGIST</td>
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<td>CHIROPRACTOR</td>
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<td>CLINICAL SOCIAL WORKER</td>
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<td>COLON AND RECTAL SURGERY</td>
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<td>DERMATOLOGY</td>
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<td>GASTROENTEROLOGY</td>
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<td>-1%</td>
<td>-1%</td>
<td>-5%</td>
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<tr>
<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>
<tr>
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<td>--------------------------</td>
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<td>HEMATOLOGY/ONCOLOGY</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>
<tr>
<td>-------------------------------</td>
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<tr>
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</tbody>
</table>

** 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 45:
- **Column A (Specialty):** Identifies the specialty for which data is shown.
- **Column B (Allowed Charges):** The aggregate estimated PFS allowed charges for the specialty based on 2014 utilization and 2015 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 2016 impact on total allowed charges of the proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- **Column D (Impact of PE RVU Changes):** This column shows the estimated 2016 impact on total allowed charges of the proposed changes in the PE RVUs.
- **Column E (Impact of MP RVU Changes):** This column shows the estimated 2016 impact on total allowed charges of the proposed changes in the MP RVUs.
- **Column F (Combined Impact):** This column shows the estimated 2016 combined impact on total allowed charges of all the changes in the previous columns

### B. Impacts of Other Proposals

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

### C. Impact on Beneficiaries

CMS notes that there are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, CMS believes that many of the proposed changes will have a positive impact and improve the quality and value of care provided to beneficiaries.

Most of the proposed policy changes would result in a change in beneficiary liability as relates to coinsurance. For example, the 2015 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $109.60 which means in 2015 a beneficiary would be responsible for 20 percent of this amount, or $21.92. Based on this proposed rule, using the estimated 2016 CF, the 2016 national payment amount in the nonfacility setting for CPT code 99203 is $110.13 which means that in 2016, the proposed beneficiary coinsurance would be $22.03.