American College of Physicians
Leading Internal Medicine, Improving Lives

# Summary of the Proposed Rule for the Medicare Physician Fee Schedule for CY 2016

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**Regulatory Impact Analysis**

For this proposed rule to maintain budget neutrality for the proposed policies, the estimated 2016 conversion factor (CF) will be $36.1096. If this CF holds throughout the year, the impact for internal medicine is a 0 percent (neutral).

**Specialty Impacts for Internal Medicine**

The specialty impact table is included below. For internal medicine and its subspecialties, the overall changes are:

| Specialty | Allowed charges (mil) | Impact of work RVU changes % | Impact of PE RVU changes % | Impact of MP RVU changes % | Combined Impact ** % |
|---|---|---|---|---|---|
| (A) | (B) | (C) | (D) | (E) | (F) |
| *** Column F may not equal the sum of columns C, D, and E due to rounding.* | | | | | |
| TOTAL | $88,408 | 0 | 0 | 0 | 0 |
| Allergy/Immunology | 220 | 0 | 1 | 0 | 1 |
| Cardiology | 6,462 | 0 | 0 | 0 | 0 |
| Critical Care | 293 | 0 | 0 | 0 | 0 |
| Endocrinology | 452 | 0 | 0 | 0 | 0 |
| Gastroenterology | 1,829 | −2 | −1 | −1 | −5 |
| Geriatrics | 213 | 0 | 0 | 0 | 0 |
| Hematology/Oncology | 1,781 | 0 | 0 | 0 | 0 |
| Infectious Disease | 655 | 0 | 0 | 0 | 0 |
| Internal Medicine | 10,964 | 0 | 0 | 0 | 0 |
| Nephrology | 2,187 | 0 | 0 | 0 | 0 |
| Neurology | 1,512 | 0 | 0 | 0 | 0 |

| Specialty | Allowed charges (mil) | Impact of work RVU changes % | Impact of PE RVU changes % | Impact of MP RVU changes % | Combined Impact ** % |
|---|---|---|---|---|---|
| Pediatrics | 59 | 0 | 0 | 0 | 0 |
| Pulmonary Disease | 1,769 | 0 | 0 | 0 | 0 |
| Rheumatology | 534 | 0 | 0 | 0 | 0 |

**Determination of Practice Expense (PE) Relative Value Units (RVUs)**

For calendar year (CY) 2016, with the incorporation of available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014, it is proposed to use a proxy practice expense per hour (PE/HR) value for interventional cardiology, as there are no Physician Practice Expense Information Survey (PPIS) data for this specialty, by crosswalking the PE/HR from Cardiology, since the specialties furnish similar services in the Medicare claims data.

The Centers for Medicare and Medicaid Services (CMS) are proposing to make modifications to two steps in the Calculating the Direct Cost PE RVUs methodology. For Step 2: Calculate the aggregate pool of direct PE costs for the current year. The proposal is to set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the proposed aggregate work RVUs. This proposed modification would result in greater stability in the relationship among the work and PE RVU components in the aggregate. It is not anticipated to affect the distribution of PE RVUs across specialties.

For Step 7 of the PE methodology, it is proposed to refine this step to use an average of the three most recent years of available Medicare claims data to determine the specialty mix assigned to each code.

Given the longstanding difficulties in acquiring accurate pricing information for equipment items, comments are being solicited on whether adding another item-specific financial variable for equipment costs could increase the accuracy of PE RVUs across the physician fee schedule (PFS).

PE Inputs for Digital Imaging Services

For CY 2015 the final rule removed the film supply and equipment items for digital imaging services and created a new equipment item as a proxy for the PACS workstation as a direct expense. CMS has proposed to update the price for the Picture Archiving and Communication System (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 invoices. Comments are solicited

as to whether it may be appropriate to include these costs as direct inputs for the associated HCPCS codes, given that many of these services are reported globally in the non-facility setting. These costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code.

Input from stakeholders, including the Relative Value Scale Update Committee (RUC), is requested about whether or not the PACS workstation used in imaging codes is the same workstation that is used in the post processing described by CPT code 76377, or if a more specific workstation should be incorporated in the direct PE input database.

Standardization of Clinical Labor Tasks

CMS is seeking comments on the clinical labor tasks that are relevant to services currently being reviewed under the misvalued code initiative. The appropriate standard minutes for the clinical labor tasks associated with: 1) services that use digital technology and 2) furnishing pathology services. CMS is proposing to eliminate the minutes assigned for the take "complete botox log" from the direct PE input database.

The Agency also is proposing to correct inconsistencies with CPT codes 22510, 22511, and 22514 in the CY 2016 proposed direct PE input database to reflect the RUC recommended values, without refinement.

Developing Non-facility Rates

Cataract surgery has generally been performed in an ambulatory surgery center (ASC) or a hospital outpatient department (HOPD). With advancements in technology, it is now believed that routine cataract surgery could be furnished in an in-office surgical suite. Comments are being requested from ophthalmologists and other stakeholders on office-based surgical cataract surgery. The RUC and other stakeholders are asked to comment on the direct practice expense inputs involved in furnishing cataract surgery in the non-facility setting in conjunction with consideration of information regarding the possibility of developing non-facility PE RUs for cataract surgery.

Endoscopic sinus surgeries can now be furnished in the non-facility setting and input is sought from stakeholders, including the RUC, about the appropriate direct PE inputs for these services.

**Determination of Malpractice Relative Value Units (RVUs)**

For CY 2016, CMS proposes to continue the current approach for determining malpractice (MP) RVUs for new/revised codes. The MP crosswalks for those new and revised codes will be subject to public comment and finalized in the CY 2016 PFS final rule.

It is proposed for CY 2016 to begin conducting annual MP RVU updates to reflect changes in the mix of clinicians providing services, and to adjust MP RVUs for risk. The specialty-specific risk factors would continue to be updated every five years using updated premium data, but would remain unchanged between the 5 year reviews.

CMS is seeking comment on: 1) updating the specialty mix for MP RVUs annually (while continuing to update specialty-specific risk factors every 5 years using updated premium data) and 2) 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.

It is proposed to maintain the 0.01 PM RVU floor for all nationally-priced PFS services that are described by base codes, but not for add-on codes. The proposal would result in all the MP RVUs for add-on codes being rounded to 0.00 where the calculated MP RVU is less than 0.005.

MP RVU Update for Anesthesia Services

For CY 2016 it is proposed to make adjustments to the anesthesia conversion factor to reflect the updated premium information collected for the five year review to appropriately update the MP resource costs for anesthesia. Public comments are invited on the proposal.

MP RVU Methodology Refinements

To address an identified necessary refinement in computing a preliminary national average premium for each specialty, it is proposed to update the calculation to use a price-adjusted premium [that is, the premium divided by the geographic practice cost index (GPCI)] in each area, and then taking a weighted average of those adjusted premiums. The CY 2016 PFS proposed rule MP RVUs were calculated in this manner.

**Potentially Misvalued Services under the Physician Fee Schedule**

CMS finalized in the CY 2015 PFS rule the high expenditure screen as a tool to identify potentially misvalued codes in the statutory category of "codes that account for the majority of spending under the PFS." In this proposed rule, CMS re-ran the screen with the same criteria finalized in last year's rule, with the exception of excluding all 10- and 90-day global periods from the process. Specifically, CMS identified the top 20 codes by specialty (using the specialties used in the regulatory impact table above) in terms of allowed charges. The Agency excluded codes that CMS has reviewed since CY 2010, those with fewer than $10 million in allowed charges, and those that describe anesthesia or E/M services. CMS is seeking input on potentially misvalued codes.

Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing Procedures

CPT has determined that moderate sedation is an inherent part of furnishing the procedure for more than 400 diagnostic and therapeutic procedures. Therefore, only the procedure code is reported when furnishing the service, and in developing RVUs for these services, CMS includes the resource costs associated with moderate sedation in the valuation of these diagnostic and therapeutic procedures. To the extent that moderate sedation is inherent in the diagnostic or therapeutic service, the Agency believes that the inclusion of moderate sedation in the valuation of the procedure is accurate. In the CY 2015 PFS proposed rule, CMS noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. The Agency continues to seek an

approach that is based on using the best available objective information about the provision of moderate sedation broadly, rather than merely addressing this issue on a code-by-code basis using RUC survey data when individual procedures are revalued. The Agency requests suggestions as to how moderate sedation should be reported and valued and how to remove from existing valuations the RVUs and inputs related to moderate sedation.

To establish an approach to valuation for all Appendix G services based on the best data about the provision of moderate sedation, CMS needs to determine the extent of the misvaluation for each code. Therefore, **CMS is seeking recommendations from the RUC and other interested stakeholders for appropriate valuation of the work associated with moderate sedation before formally proposing an approach that allows Medicare to adjust payments based on the resource costs associated with the moderate sedation or anesthesia services that are being furnished.**

The anesthesia procedure codes 00740 (Anesthesia for procedure on gastrointestinal tract using an endoscope) and 00810 (Anesthesia for procedure on lower intestine using an endoscope) are used for anesthesia furnished in conjunction with lower GI procedures. In reviewing Medicare claims data, we noted that a separate anesthesia service is now reported more than 50 percent of the time that several types of colonoscopy procedures are reported. **Given the significant change in the relative frequency with which anesthesia codes are reported with colonoscopy services, CMS believes the relative values of the anesthesia services should be reexamined. Therefore, the Agency is proposing to identify CPT codes 00740 and 00810 as potentially misvalued.**

<u>Improving the Valuation and Coding of the Global Package</u>

In the CY 2015 PFS final rule, CMS finalized a policy to transition all 10-day and 90-day global codes to 0-day global codes to improve the accuracy of valuation and payment for the various components of global surgical packages, including pre- and post-operative visits and performance of the surgical procedure. The Agency believes that valuing global codes that package services together without objective, auditable data on the resource costs associated with the components of the services contained in the packages may significantly skew relativity and create unwarranted payment disparities within PFS fee-for-service payment. CMS stated the Agency's belief that transforming all 10- and 90-day global codes to 0-day global codes would:

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

The Medicare Access and CHIP Reauthorization Act (MACRA), enacted into law on April 16, 2015, prohibits the Secretary from implementing the policy established in the CY 2015 PFS final rule and requires CMS to develop through rulemaking a process to gather information needed to value surgical services from a representative sample of physicians and requires that the data collection shall 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. This information must be reported on claims at the end of the global period or in another manner specified by the Secretary. Every four years, CMS must reassess the value of this collected information, and the Agency may discontinue the collection if the Secretary determines that it has adequate information from other sources in order to accurately value global surgical services.

Beginning in CY 2019, CMS must use the information collected, as appropriate, along with other available data to improve the accuracy of valuation of surgical services under the PFS. MACRA authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information until the required information is reported. **CMS is soliciting comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished by the clinician reporting the procedure code during the current post-operative periods) needed to increase the accuracy of the values for surgical services. The Agency is also seeking comment on the most efficient means of acquiring these data as accurately and efficiently as possible.** For example, the Agency seeks information on the extent to which individual clinicians or practices may currently maintain their own data on services, including those furnished during the post-operative period, and how CMS might collect and objectively evaluate those data for use in increasing the accuracy of the values beginning in CY 2019. CMS will use the information from the public comments to help develop a proposed approach for the collection of this information in future rulemaking.

**CMS is seeking public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and post-operative care, including the follow-up care during post-operative days. The Agency is particularly interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. For example, CMS seeks information from stakeholders on whether (both qualitatively and quantitatively) postoperative visits differ from other E/M services. The Agency is also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during post-operative care.** CMS intends to provide further opportunities for public feedback prior to developing a proposal for CY 2017 to collect this required data. The Agency also seeks comments regarding stakeholder interest in the potential for an open door forum, town hall meetings with the public, or other avenues for direct communication regarding implementation of these provisions of MACRA.

**Refinement Panel**

Beginning in CY 2016, CMS is proposing to eliminate the refinement panel and instead publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. With this change the proposed codes adopted in the CY 2015 final rule are being valued in the CY 2016 PFS proposed rule. This process will allow for stakeholder comments at the time of proposal of valuation for codes and when the value is set.

**Improving Payment Accuracy for Primary Care and Care Management Services**

CMS recognizes that care management is a critical component of primary care. In CY 2013 PFS CMS adopted a policy to pay separately for transitional care management (TCM) involving the transition of a beneficiary from care furnished by a treating physician during an inpatient stay to care furnished by the beneficiary's primary physician in the community. The CY 2015 PFS finalized paying separately for chronic care management (CCM) services furnished to Medicare beneficiaries with two or more chronic conditions. Stakeholders have asserted that these codes do not explicitly account for all of the time and intensity of cognitive efforts required to manage these patients. Examples of these efforts would be the work involved for medication reconciliation, the assessment and integration of numerous data points, effective coordination of care among multiple other clinicians, collaboration with team members, continuous development and modification of care plans, patient or caregiver education, and the communication of test results. **Input is requested on how best to balance access to TCM and CCM services and the administrative burden for clinicians who provide these services.**

**Comments specific to the CCM code also are requested to provide information regarding the circumstances under which the service is provided, the range of minutes per month, and objective data regarding the resource costs associated with providing the service.**

**The Agency also is interested in receiving comments on ways to recognize different resources (particularly in cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the codes that describe the broader range of E/M services.** They are particularly interested in codes that could be used in addition to, not instead of, the current E/M codes. These codes could be similar to current add on codes and allow for reporting of additional time and intensity of the cognitive work.

"Collaborative Care" is an evidence based approach to caring for patients with common behavioral health conditions. Collaborative Care is typically provided by a primary care team, consisting of a primary care provider and a care manager, who works in collaboration with a psychiatric consultant. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations. **CMS is seeking comment on how coding under the PFS might facilitate appropriate valuation for services delivered in a collaborative care model.** An example would be a collaborative care code with requirements similar to those used for CCM services and whether such a code could be reported in conjunction with CCM or other E/M services. Or should the collaborative care model be implemented through a Center for Medicare and Medicaid Innovation (CMMI) demonstration to most effectively support this model?

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

The Protecting Access to Medicare Act of 2014 (PAMA), enacted on April 1, 2014, established an annual target for reductions in PFS expenditures that should result from adjustments to relative values of misvalued codes. This section of PAMA applied to calendar years (CYs) 2017 through 2020 and set the target at 0.5 percent of the estimated amount of expenditures under the PFS for each of those 4 years. Under PAMA, if the estimated net reduction for a given year is equal to or greater than the target, then the reduced expenditures will be redistributed in a budget-neutral manner within the PFS—with any reductions exceeding this target being treated as a net reduction for the succeeding year. However, if the estimated net reduction in expenditures for a year is less than the target, then fee schedule payments for the year are reduced by the difference between the target and the amount of misvalued services identified in that year. However, the Achieving a Better Life Experience (ABLE) Act, which was passed in December 2014, doubles the amount of that target, and therefore the amount at risk to be cut to 1 percent cut on all Medicare reimbursements. The ABLE Act also moves up the start date for this target to be met to 2016. Following the 1 percent target for 2016, it sets a 0.5 percent target for 2017 and 2018.

In order to meet the requirements initially established by PAMA and then accelerated by the ABLE Act, CMS is proposing to define the reduction in expenditures as the net result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values (both increases and decreases in values). The agency notes that this definition would incorporate all reduced expenditures from revaluations for services that are deliberately addressed as potentially misvalued codes, as well as those for services with broad-based adjustments that are redefined through coding changes.

Many codes have also undergone changes in values measured over 3 years rather than 2 years—with the original value in place the first year, the interim value in the second year, and the final value in the third year. CMS outlines a number of potential problems with including these codes in the calculation for the 2016 target and so therefore is proposing to exclude any code value changes for CY 2015 interim values from the calculation of the CY2016 misvalued code target.

Further, CMS is proposing to use the approach of comparing total RVUs (by volume) for the relevant set of codes in the current year to the update year, and then dividing that by the total RVUs (by volume) for the current year. The agency is seeking comment on this approach.

**Overall, the proposed approach results in a net reduction of approximately 0.25 percent of the estimated total amount of expenditures under the fee schedule for CY 2016. Therefore, if the proposed approaches described above are carried out, CMS will be 0.75 percent less than the target outlined in the ABLE Act and would result in overall fee schedule payments being reduced by that difference.**

**Phase-in of Significant RVU Reductions**

PAMA specifies that for services that are not new or revised codes, 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 previous year, the adjustments in work, PE, and MP RVUs should be phased in over a 2-year period. PAMA required that this phase-in process begin in 2017; however, the ABLE Act accelerated the phase-in to begin in CY 2016.

CMS is proposing to apply this 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. The agency is also proposing to estimate the total RVUs for a service prior to the budget-neutrality redistributions that will result from implementing phase-in values. Additionally, rather than phasing-in these value changes with an approach of 50 percent the first year and 50 percent the second year (which could result in some value changes near, but just below, the 20 percent threshold experiencing a significantly higher reduction in one year than other codes values that are at or just above the 20 percent threshold), **CMS is proposing to consider a 19 percent reduction as the maximum first year reduction, with any remaining reduction occurring in the second year. The agency is seeking comment on this approach.**

CMS is also proposing to consider the RVUs for different sites of service and for different components (professional and technical) independently in determining whether or not a code meets the 20 percent threshold to be phased in over 2 years. However, in cases where the PE RVUs are different for a code based on site of service, CMS is proposing to apply the adjustments for the 2-year phase-in of the code only to the PE RVUs—this is intended to mitigate the impact of significant reductions of total RVUs for services furnished by individual clinicians.

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

(CY 2016 only)

Computed Tomography (CT) services identified by CPT codes 70450-70498, 71250-71275, 72125-72133, 72191-72194, 73200-73206, 73700-73706, 74150-74178, 74261-74263, and 75571-75574 furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013 must include modifier "CT." That modifier will result in payment reduction by 5 percent in 2016 and 15 percent in 2017.

**Valuation of Specific Codes**

Misvalued Code Changes for Lower GI Endoscopy Services

In the CY 2015 PFS final rule with comment period, CMS delayed valuing the lower GI codes and indicated that they would propose values for these codes in the CY 2016 proposed rule. CMS has acknowledged the changes in practice patterns and the need to establish a uniform approach to valuation for all services that currently include moderate sedation. **CMS is seeking recommendations from the RUC and other interested stakeholders for valuation of**

**the work associated with moderate sedation alone before proposing payment based on the resource costs associated with the moderate sedation of anesthesia services that are being furnished.** Additionally, CMS is proposing to identify anesthesia procedure codes 00740 and 00810 as potentially misvalued.

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

Advance Care Planning

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning (ACP) services: CPT code 99497 [Advance care planning 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 member(s) and/or surrogate]; and an add-on CPT code 99498 [Advance care planning 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 profession; each additional 30 minutes (List separately in addition to code for primary procedure)].

For CY 2016, CMS is proposing to assign these codes a PFS status indicator "A" which is defines as: "Active code. These codes are separately payable under the PFS. There will be RVUs for codes with this status." The presence of an A indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy. **CMS is proposing to adopt the RUC–recommended values for CPT codes 99497 and 99498 beginning in CY 2016 and will consider all public comments that they receive on this proposal.** Advance care planning code(s) should be reported when the described service is reasonable and necessary for the diagnosis or treatment of an injury or illness. However, advance care planning services do not necessarily have to occur on the same day as an E/M service.

**Medicare Telehealth Services**

CMS received several requests in CY 2014 to add various Medicare telehealth services effective for CY 2016. The Agency proposes to add prolonged service inpatient CPT codes 99356 and 99357 and ESRD-related services 90933 through 90936 to the list of Medicare telehealth services beginning in CY 2016 on a category 1 basis. Category 1 involves services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services.

CMS declined to add codes for non-covered services for which no payment may be made under the PFS. The request for CPT code 99490 (chronic care management services) was deemed not appropriate for consideration as a Medicare telehealth service due to the fact that the service can be furnished without the beneficiary's face-to-face presence, using any number of non-face-to-face means of communication. Requests for services to be considered during the PFS rulemaking for CY 2017 must be submitted and received by December 31, 2015.

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

In the CY 2014 PFS final rule, CMS required that as a condition for Medicare Part B payment, all incident to services must be furnished in accordance with applicable state law. The definition of auxiliary personnel was also amended to require that the individual who provides the incident to services must meet any applicable requirements to provide such services (including licensure) imposed by the state in which the services are furnished. CMS is proposing to revise the regulations to specify the requirement that physicians or other clinicians who bill for incident to services are also directly supervising the auxiliary personnel who are providing the incident to services. CMS is also proposing to amend the regulation 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 Office of Inspector General or who have had their enrollment revoked for any reason.

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

CMS is proposing to revise the Medicare Claims Processing Manual (Pub.100-4, Chapter 13, Section 90.3) to clarify that when more than one patient is x-rayed at the same location, the single transportation payment is to be prorated among all patients (Medicare Parts A and B, and non–Medicare) receiving portable x-ray services during that trip, regardless of their insurance status.

**Technical Correction: Waiver of Deductible for Anesthesia Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test**

CMS is proposing make a technical correction to expressly recognize anesthesia services by amending the regulation to ensure that both surgical or anesthesia services furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test will be exempt from the deductible requirement when furnished on the same date as a planned colorectal screening test. This proposal would be effective retroactive to January 1, 2015.

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

Currently neither RHCs and FQHCs nor individual clinicians working at RHCs and FQHCs are allowed to bill under the PFS. The proposed rule would provide an additional payment for the costs of CCM services that are not already captured in the RHC AIR or the FQHC PPS payment beginning on January 1, 2016. CMS is soliciting comments on how the CCM services payment requirements could be adapted for RHCs and FQHCs to promote integrated and coordinated care. The requirements proposed for FQHCs and RHCs are consistent with those finalized in the CY 2015 PFS final rule. The RHC and FQHC face-to-face requirement will be waived when CCM services are furnished to a RHC or FQHC patient. The eligible beneficiary must be informed and provide his or her written agreement for CCM services. A minimum of 20 minutes of qualifying CCM services would be provided 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 clinician can bill this code per month, and there are restrictions regarding the billing of other overlapping care management services during the same service period. Coinsurance would be applied as applicable to FQHC claims, and coinsurance and deductibles would apply as applicable to RHC claims.

**Appropriate Use Criteria for Advanced Diagnostic Imaging Services**

In PAMA, Congress required that clinicians who order advanced diagnostic imaging services consult appropriate use criteria (AUC) via a clinical decision support mechanism. CMS is required to specify AUC from among those developed or endorsed by national medical professional specialty societies and provider-led entities not later than November 15, 2015.

PAMA also requires CMS to approve clinical decision support mechanisms by April 1, 2016, additional information to be collected on the Medicare claim form by January 1, 2017, and that the claims information be used to develop a prior authorization program by January 1, 2020.

CMS is proposing a number of definitions and processes for areas of the statute that require clarification. These include a definition of an AUC, a specified process to develop an AUC, and a definition of "provider-led entity," which defines those entities qualified to develop or endorse an AUC that qualifies under the statute. The rule also proposes processes to establish "priority clinical areas" for the AUC to address and to identify a non-evidence-based AUC. The proposed definitions and processes are indicated in the table below:

| Title of Proposed Definition or Process | Proposed Definition or Process |
|---|---|
| Appropriate Use Criteria (AUC) Definition | Criteria developed or endorsed only 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 must be evidence-based. AUC are a collection of individual appropriate use criteria. Individual criterion is 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). |
| Priority Clinical Area | Clinical topics, clinical topics and imaging modalities, or imaging modalities identified by CMS through annual rulemaking and in consultation with stakeholders that may be used in the determination of outlier ordering professionals. |
| Provider-led Entity | A national professional medical specialty society or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare. |
| Specified Applicable AUC | AUC developed, modified, or endorsed by a qualified provider-led entity. |

| Title of Proposed Definition or Process | Proposed Definition or Process |
|---|---|
| Required Process for Qualified Provider-led Entities for the Development of an AUC | Provider-led entities must follow appropriate, evidence-based processes for the development of AUC and demonstrate adherence to the requirements below to be qualified by CMS. AUC developed, modified or endorsed by qualified PLEs are specified applicable AUC. Qualified provider-led entities may develop AUC, modify AUC developed by another entity, or provide endorsement to AUC developed by other entities.<br>(1) Requirements for developing, modifying or endorsing AUC. All of the following must be met:<br>(i) An evidentiary review process that includes:<br>(A) A systematic literature review of the clinical topic and relevant imaging studies; and<br>(B) An assessment of the evidence using a formal published and widely recognized methodology for grading evidence. Consideration of relevant published consensus statements by professional medical specialty societies must be part of the evidence assessment.<br>(ii) At least one multidisciplinary team with autonomous governance, decision making, and accountability for developing, modifying, or endorsing AUC. At a minimum the team must be comprised of three members including one with expertise in the clinical topic related to the criterion and one with expertise in the imaging modality related to the criterion.<br>(iii) A publicly transparent process for identifying potential conflicts of interest of members on the multidisciplinary team. The following information is identified and made timely available in response to a public request for a period of not less than five years, coincident with the AUC publication of the related recommendation:<br>(A) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC. This may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.<br>(B) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or |

| Title of Proposed Definition or Process | Proposed Definition or Process |
|---|---|
| | organizations that may financially benefit from the AUC.<br>(iv) Individual criteria must be published on the provider-led entity's website and include an identifying title, authors, and key references used to establish the evidence. If relevant to a CMS identified priority clinical area, such a statement must be included.<br>(v) Key points in individual criteria must be identified as evidence-based or consensus based, and graded in terms of strength of evidence using a formal, published and widely recognized methodology.<br>(vi) The provider-led entity must have a transparent process for the timely and continual updating of each criterion.<br>(vii) The provider-led entity's process for developing, modifying or endorsing AUC is publicly posted on the entity's website. |
| Process to Identify Qualifying Provider-led Entities | Provider-led entities must meet all of the following criteria:<br>(i) Provider-led entities must submit an application to CMS that documents adherence to each of the AUC development requirements outlined in this section;<br>(ii) Applications will be accepted by CMS only from provider-led entities that meet the definition in this section;<br>(iii) Applications must be received by CMS annually by January 1;<br>(iv) All approved provider-led entities from each year of submissions will be posted to the CMS website by June 30; and<br>(v) Qualified provider-led entities are required to re-apply every 6 years. The application must be submitted by January 1 during the 5th year of their approval. |
| Process to Identify Priority Clinical Areas | (1) CMS must identify priority clinical areas through annual rulemaking and in consultation with stakeholders.<br>(2) CMS will consider incidence and prevalence of disease, volume variability of utilization, and strength of evidence for imaging services. CMS will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.<br>(3) The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.<br>(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals as defined in the statute. |
| Process to Identify Non-evidence Based AUC | (1) CMS will accept public comment to facilitate identification of individual or groupings of AUC that fall within a priority clinical area and are not evidence-based. CMS may also independently identify AUC of concern.<br>(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC. |

**Physician Compare**

This section of the proposed rule continues the phased-in approach to developing the Physician Compare website, which includes information on physicians and other eligible professionals (EPs) enrolled in the Medicare program. CMS proposes to make a broader set of quality measures available for publication on the website.

CMS proposes to expand the section on each individual EP and group practice profile page to include a green check mark to indicate those EPs and groups who received an upward adjustment for the value modifier (VM). The 2018 VM would be based on the 2016 payment year quality reporting data. CMS would include information on physician compare on those EPs and groups who will receive 2018 VM upward adjustments no earlier than late 2017. CMS believes that including the check mark is a positive first step in making important information available to consumers in a way that is most likely to be accurately interpreted and beneficial.

In 2015, an indicator was included if EPs satisfactorily reported four individual PQRS cardiovascular prevention measures. CMS now proposes to also include an indicator for EPs who satisfactorily report on the new Cardiovascular Prevention measures group under the physician quality reporting system (PQRS) (if the measures group is finalized).

CMS proposes to continue to make available for public reporting on Physician Compare on an annual basis the performance rate for all PQRS group practice reporting option (GPRO) measures (across all reporting mechanisms), all measures reported by Shared Savings Program accountable care organizations (ACOs), and all PQRS measures for individual EPs (across all reporting mechanisms).

CMS proposes to continue to make available for public reporting individual EP-level qualified clinical data registry (QCDR) PQRS and non-PQRS measure data (that have been collected for at least a full year). The Agency also proposes to make available for public reporting group practice-level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year (this is contingent on CMS finalizing the proposal to allow group practice QCDR reporting for PQRS). Each QCDR would be required to declare during self-nomination if it plans to post data on its own website and allow Physician Compare to link to it or will provide data to CMS for public reporting on Physician Compare.

**Summary of Proposed Measure and Participation Data for Public Reporting**

| Data Collection Year | Data Publication Year | Data Type | Reporting Mechanism | Proposed Quality Measures and Data for Public Reporting |
|---|---|---|---|---|
| 2016 | 2017 | PQRS, PQRS GPRO, EHR, and Million | Web Interface, EHR, Registry, Claims | Include an indicator for satisfactory reporters under PQRS, participants in the EHR Incentive Program, and EPs who satisfactorily report the |

| Data Collection Year | Data Publication Year | Data Type | Reporting Mechanism | Proposed Quality Measures and Data for Public Reporting |
|---|---|---|---|---|
| | | Hearts | | Cardiovascular Prevention measures group proposed under PQRS in support of Million Hearts. |
| 2016 | 2018 | PQRS, PQRS GPRO | Web Interface, EHR, Registry, Claims | Include an indicator for individual EPs and group practices who receive an upward adjustment for the VM. |
| 2016 | 2017 | PQRS GPRO | Web Interface, EHR, Registry | 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.<br><br>Publicly report an item-level benchmark, as appropriate. |
| 2016 | 2017 | ACO | Web Interface, Survey Vendor Claims | All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs. |
| 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.<br><br>Publicly report an item-level benchmark, as appropriate. |
| 2016 | 2017 | QCDR Data | QCDR | All individual EP and group practice QCDR measures. |
| 2016 | 2017 | Utilization Data | Claims | Utilization data for individual EPs in the downloadable database. |
| 2016 | 2017 | PQRS, PQRS | Web Interface, | The following data for group practices and individual EPs in the |

| Data Collection Year | Data Publication Year | Data Type | Reporting Mechanism | Proposed Quality Measures and Data for Public Reporting |
|---|---|---|---|---|
| | | GPRO | EHR, Registry, Claims | downloadable database:<br>• 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.<br>• A notation of the payment adjustment received based on the cost and quality tiers.<br>• An indication if the individual EP or group practice was eligible to but did not report quality measures to CMS. |

New Benchmarking Methodology

CMS proposes to report publicly on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABC$^{TM}$) methodology annually based on the PQRS performance rates most recently available (e.g., in 2017 report a benchmark derived from 2016 PQRS performance rates). This would only apply to measures deemed valid and reliable and that are reported by enough EPs or group practices to produce a valid result.

ABC$^{TM}$ is a data-driven methodology that allows accounting for all of the data collected for a quality measure, evaluation of the top performers, and then use of that to set a point of comparison for all of those groups or individual EPs who report the measure.

ABC$^{TM}$ starts with pared-mean (the mean of the best performers on a given measure for at least 10 percent of the patient population, not the population of reporters). To find this, CMS will rank order from highest to lowest performance score EPs or groups (as appropriate to the measure being evaluated). CMS will subset the list by starting with the best performers and moving down the list until enough reporters have been selected to represent 10 percent of all patients in the denominator across all reporters.

The benchmark is derived by calculating the total number of patients in the highest scoring subset receiving the intervention or desired level of care and dividing by the total number of patients within the subset. This produces the benchmark that represents the best care provided to the top 10 percent of patients.

To account for low denominators, ABC™ calls for calculation of an adjusted performance fraction (APF), a Bayesian estimator. The AFP is calculated by dividing that actual number of patients receiving the intervention or the desired level of care plus 1 by the total number of patients in the sample plus 2. This ensures that very small sample sizes do not over influence the benchmark and allow all data to be included in the benchmark calculation. To ensure that a sufficient number of cases are included by mean performance percent, ABC™ provides a minimum sufficient denominator (MSD) for each performance level. Together this ensures that all cases are appropriately accounted for and adequately figured into the benchmark.

CMS also proposes to use the ABC™ methodology to generate a benchmark that can be used to systematically assign stars for the Physician Compare 5 star rating. According to CMS, the ABC™ has been historically well received by health care professionals and entities it is measuring because the benchmark represents quality while being both realistic and achievable; it encourages continuous quality improvement; and, it is shown to lead to improved quality of care.

CMS proposes to continue to make available for public reporting all patient experience data from CAHPS for PQRS for groups of two or more EPs who meet the specified sample size requirements and collect data via a CMS-certified CAHPS vendor.

CMS proposes to add to the Physician Compare downloadable database the 2018 VM quality tiers for cost and quality, based on performance year 2016 data, noting if the group practice or EP is high, low, or average on cost and quality. CMS also proposes to include a notation of the payment adjustment received based on the cost and quality tiers and an indication if the EP or group was eligible to report quality measures but did not.

CMS also proposes to include utilization data generated from Part B claims on services and procedures provided to Medicare beneficiaries in the downloadable database by HCPCS code. MACRA required the Agency to integrate utilization data on Physician Compare beginning with 2016. CMS believes these data will be very useful to the health care industry and researchers and others who can interpret them and use them in meaningful analysis.

CMS proposes adding Board Certification information to Physician Compare from the American Board of Optometry and American Osteopathic Association. The website already lists certification information from the American Board of Medical Specialties.

For future rulemaking, CMS is seeking comment on:

- The types of quality measure that will help fill gaps and meet the needs of stakeholders and would benefit future reporting on Physician Compare;
- Adding Medicare Advantage (MA) information to group and individual EP profile pages (specifically which MA plans are accepted with a link to more information on the medicare.gov plan finder site);
- Including additional VM cost and quality data on Physician Compare (i.e., an indicator

for downward or neutral VM adjustments and cost composite or other VM cost measure data);

- Including open payments data on individual EP profile pages; and
- Including EP and group practice-level quality measure data stratified by race, gender, and ethnicity if feasible and appropriate.

**Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System**

CMS proposes to include the following reporting mechanisms for PQRS performance year 2016 consistent with previous policy: claims; qualified registry; EHR (including direct EHR products and EHR data submission vendor products); the GPRO web interface; certified survey vendors, for CAHPS for PQRS survey measures; and QCDR. The complete requirements for satisfactorily reporting PQRS for each reporting mechanism for performance year 2016 are outlined in the table below.

Beginning in 2016, CMS proposes to allow QCDRs to submit quality measures data for group practices. The Agency also proposes to require group practices with 25 or more EPs that register to participate in the PQRS GPRO and select the web interface as the reporting mechanism to select a CMS-certified vendor to collect Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS data for 2016, whenever possible. This was previously only required for groups with 100 or more EPs. CMS is excluding group practices that report using the qualified registry, EHR, or QCDR mechanisms from this requirement. Group practices that are required or voluntarily elect to report CAHPS will need to select and pay a CMS-certified vendor to administer the surveys. The administration of the CAHPS for PQRS survey will only contain 6 months of data.

For the 2016 PQRS performance year, if EP sees at least 1 Medicare patient in a face-to-face encounter, the EP would be required to report on at least one measure in the cross-cutting measures set. CMS proposes to determine whether a face-to-face encounter occurred by assessing whether the EP billed for services under the PFS that are associated with face-to-face encounters (i.e., general office visit codes, outpatient visit codes, and surgical procedures). Telehealth visits would not count as face-to-face for these purposes.

It is important to note that all EPs that do not meet the criteria for satisfactory reporting for the 2016 PQRS performance year will be subject to the negative 2 percent adjustment in PQRS payment adjustment year 2018, with no exceptions.

**Summary of Individual and Group Practice Reporting Requirements for Satisfactory PQRS Reporting for CY 2016**

| Group Practice Size | Measure Type | Reporting Mechanism | Satisfactory Reporting/ Participation Criteria |
|---|---|---|---|
| Individual/Solo | Individual Measures | Claims, Qualified Registry | Claims Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least |

| Group Practice Size | Measure Type | Reporting Mechanism | Satisfactory Reporting/ Participation Criteria |
|---|---|---|---|
| | | | 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, 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 percent performance rate would not be counted. |
| Individual/Solo | Individual Measures | Direct EHR Product or EHR Data Submission Vendor Product | Report 9 measures covering at least 3 of the NQS domains. If an EP'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 EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least 1 measure for which there is Medicare patient data. |
| Individual/Solo | Measures Groups | Qualified Registry | Report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted. |
| Individual/Solo | Individual PQRS Measures and/or Non-PQRS Measures Reportable Via 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 EP's patients. Of these measures, the EP would report on at least 2 outcome measures, OR, if 2 outcomes |

| Group Practice Size | Measure Type | Reporting Mechanism | Satisfactory Reporting/ Participation Criteria |
|---|---|---|---|
| | | | 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. |
| 25+ EPs (if CAHPS does not apply) | Individual GPRO Measures in GPRO Web Interface | GPRO Web Interface | 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. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data. |
| 25+ EPs (if CAHPS for PQRS applies) | Individual GPRO Measures in GPRO Web Interface + CAHPS for PQRS | GPRO Web Interface + 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. 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 |

| Group Practice Size | Measure Type | Reporting Mechanism | Satisfactory Reporting/ Participation Criteria |
|---|---|---|---|
| | | | 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. Please note that, if the CAHPS for PQRS survey is applicable to a group practice who reports quality measures via the GPRO web interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the GPRO web interface measures. |
| 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 least 3 NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. |
| 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 |

| Group Practice Size | Measure Type | Reporting Mechanism | Satisfactory Reporting/ Participation Criteria |
|---|---|---|---|
| | | | 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 Measures and/or Non- | QCDR | Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report |

| Group Practice Size | Measure Type | Reporting Mechanism | Satisfactory Reporting/ Participation Criteria |
|---|---|---|---|
| | PQRS Measures Reportable Via QCDR | | each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least 2 outcome measures, OR, if 2 outcomes 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. |

The ACA requires CMS to report data on race, ethnicity, sex, primary language, and disability status. CMS intends to require collection of these data elements within each PQRS reporting mechanism in the future. **CMS is seeking comments on the facilitators and obstacles clinicians and vendors may face in collecting and reporting these attributes and on preference for a phased-in approach (i.e., starting with a subset of measures versus requiring across all possible measures and reporting mechanisms).**

Selection of Quality Measures for 2016 and Beyond

In selecting measures, CMS is required to select measures that have been endorsed by a consensus organization that has a contract with CMS, which is currently the National Quality Forum (NQF). However, in the case of a specified area or medical topic determined appropriate by CMS for which a feasible and practical measure has not been endorsed by NQF, the Agency may consider measures that have not been endorsed as long as due consideration has been given to measures that have been endorsed or adopted by a consensus organization. The statute is silent as to how measures that are submitted to the contracted consensus organization (NQF) are developed. The steps for developing measures may be carried out by a variety of different organizations, and CMS does not believe that there need to be specific restrictions on the makeup of organizations doing measures development (i.e., that they are physician-controlled organizations).

Additionally, CMS must establish a pre-rulemaking process under which certain steps occur including convening multi-stakeholder groups to provide input on the selection of measures. This is currently done by NQF through the Measures Applicability Partnership (MAP). CMS must make publicly available by December 1 of each year the measures that it is considering for selection, and NQF must provide CMS with the MAP's input by February 1.

Aside from NQF endorsement, CMS requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- Measures that are not duplicative of another existing or proposed measures

- Measures that are further along in development than a measure concept.
- The Agency is not accepting claims-based-only reporting measures in this process.
- Measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that include the NQS domain for care coordination and communication.
- Measures that include the NQS domain for patient experience and patient-reported outcomes.
- Measures that address efficiency, cost and resource use.

CMS proposes to add 46 new individual measures to PQRS for the 2016 performance period and to remove 12 measures. The Agency proposes to add four new cross-cutting measures for PQRS reporting in CY 2016:

- Preventive Care and Screening: Unhealthy Alcohol Use Screening and Brief Counseling;
- Breast Cancer Screening;
- Falls: Risk Assessment; and
- Falls: Plan of Care.

CMS proposes to add three new measures groups for PQRS reporting in CY 2016:

- Multiple Chronic Conditions Measures Group;
- Cardiovascular Prevention Measures Group (Million Hearts); and
- Diabetic Retinopathy Measures Group.

**Request for Input on Provisions Included in MACRA**

The CMS proposed rule for the Medicare Physician Fee Schedule for Calendar Year (CY) 2016 contained a request for comments on several components of MACRA for both the Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) tracks as outlined below. In addition to these provisions, CMS also solicited comments and recommendations on any additional provisions of MACRA that are not specifically listed in the proposed rule.

Low-Volume Threshold

Under MACRA, the HHS Secretary is required to set a low-volume threshold for the purpose of excluding certain clinicians from MIPS. The Secretary may use any of the following criteria in setting the low-volume threshold:

- Minimum number of individuals enrolled under Medicare Part B who are treated by the EP for the performance period involved;
- Minimum number of items and services furnished to individuals enrolled under Medicare Part B by such EP for such performance period; and
- Minimum amount of allowed charges billed by such EP under Medicare Part B for such performance period.

**CMS is seeking comment as to what would be an appropriate low-volume threshold for purposes of excluding certain EPs from the definition of a MIPS EP. The Agency is also seeking comment as to whether CMS should consider establishing a low-volume threshold using more than one or a combination of factors or, alternatively, whether CMS should focus on establishing a low-volume threshold based on one factor.** CMS invites comments on which factors to include, individually or in combination, in determining a low-volume threshold.

CMS currently uses low-volume thresholds in other reporting programs. For example, EPs and acute care hospitals must meet certain Medicaid patient volume thresholds to be eligible for the Medicaid EHR Incentive Program (in general, 30 percent for EPs and 10 percent for acute care hospitals). The Agency would consider proposing similar thresholds, such as to exclude EPs that do not have at least 10 percent of their patient volume derived from Medicare Part B encounters from participating in the MIPs. CMS seeks comment as to whether this would be an appropriate low-volume threshold for the MIPS. In addition, the Agency invites comments on the applicability of existing low-volume thresholds used in other CMS reporting programs toward MIPs.

Clinical Practice Improvement Activities

Under MIPS, EPs are evaluated in terms of four different performance categories for purposes of determining the composite performance score: quality, resource use, clinical practice improvement activities, and meaningful use of electronic health records. In the law, clinical practice improvement activities are defined as activities that relevant EP 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. Clinical practice improvement categories, specified by the Secretary, must include at least the following subcategories:

- **Expanded practice access**, such as same day appointments for urgent needs and afterhours access to clinician advice;
- **Population management**, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry;
- **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;
- **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;
- **Patient safety and practice assessment**, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification; and
- **Participation in an alternative payment model**.

**CMS is seeking comments on what activities could be classified as clinical practice improvement activities according to this definition.**

Alternative Payment Models

MACRA introduces a framework for promoting and developing APMs and providing incentive payments for EPs who participate in APMs, with payment implications for EPs beginning in 2019. CMS is broadly seeking public comment on the topics in this section through this proposed rule. In preparation to implement the changes introduced by the section of MACRA on Promoting Alternative Payment Models, the Agency intends to publish questions for public comment on these amendments through a forthcoming Request for Information (RFI). The Promoting Alternative Payment Models section includes the following provisions:

- Increasing Transparency of Physician-Focused Payment Models and Criteria and Process for Submission and Review of Physician-focused Payment Models;
- Incentive Payments for Participation in Eligible Alternative Payment Models;
- Encouraging Development and Testing of Certain Models;
- A study on Integrating Medicare Alternative Payment Models in the Medicare Advantage payment system; and
- Study and Report on Fraud Related to Alternative Payment Models under the Medicare Program.

CMS intends to publish specific questions in the forthcoming RFI on topics within these provisions, including the following:

- 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-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.

**In anticipation of the future RFI and subsequent notice and comment rulemaking, CMS welcomes comments on approaches to implementing any of the topics listed in this section, including in provisions not enumerated above, and any other related concerns.**

**Electronic Clinical Quality Measures (eCQM) and Certification Criteria and Electronic Health Record (EHR) Incentive Program— Comprehensive Primary Care (CPC) Initiative and Medicare Meaningful Use Aligned Reporting**

Certification Requirements for Reporting Electronic Clinical Quality Measures (eCQMs) in the EHR Incentive Program and PQRS

Physicians and other EPs participating in PQRS and the EHR Incentive Programs under the 2015 Edition must possess EHRs that have been certified to report eCQMs according to the format that CMS requires for submission. To allow EPs to upgrade to 2015 Edition CEHRT before 2018, CMS proposes to revise the CEHRT definition for 2015 through 2017 to require that EHR technology is certified to report eCQMs, in accordance with the optional certification, in the

format that CMS can electronically accept. Rather than requiring certification for each eCQM, this would require technology to be certified to use the HL7 QRDA Category I and III standards and the optional CMS "form and manner." CMS also proposes to revise the CEHRT definition for 2018 and subsequent years to require that EHR technology is certified to report eCQMs using the same standards. The proposed CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule allows EPs to use 2014 Edition or 2015 Edition certified EHR technology.

The Agency also proposes to revise the CEHRT definition for 2018 and subsequent years to require that EHR technology is certified to report eCQMs using the same standards. These proposed revisions would apply for EPs, eligible hospitals, and CAHs. CMS is proposing these amendments to ensure that EPs participating in PQRS and the EHR Incentive Programs under the 2015 Edition possess EHRs that have been certified to report eCQMs according to the format that CMS requires for submission.

EHR Incentive Program-Comprehensive Primary Care (CPC) Initiative Aligned Reporting

Under this initiative, CMS pays participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, state, and other federal insurance plans are also offering enhanced support to primary care practices that provide high-quality primary care. CPC practice sites are required to report to CMS a subset of the CQMs that were finalized in the EHR Incentive Program Stage 2 final rule for EPs beginning in CY 2014. For 2016, CMS proposes to require CPC practice sites to submit at least 9 CPC CQMs that cover 3 domains (rather than the current requirement of 2 domains). CMS believes that reporting across 3 domains is reasonable given the increased number of measures in the CPC eCQM set, the sufficient time that CPC practices have had to upgrade their systems, and the fact that this requirements aligns with what is required for the Medicare EHR Incentive Program CQM reporting.

CMS also proposes that for CY 2016, EPs who are part of a CPC practice site and are in their first year of demonstrating MU may use the CPC group reporting option to report their CQMs electronically instead of reporting CQMs by attestation though the EHR Incentive Program's Registration and Attestation System. However, EPs who choose this CPC group reporting option must use a reporting period for CQMs of one full year (not 90 days), and the data must be submitted during the submission period from January 1, 2017 through February 28, 2017. **This means that EPs who elect to electronically report through the CPC practice site cannot successfully attest to meaningful use prior to October 1, 2016 (the deadline established for EPs who are first-time meaningful users in CY 2016) and therefore will receive reduced payments under the PFS in CY 2017 for failing to demonstrate meaningful use if they have not applied and been approved for a significant hardship exception under the EHR Incentive Program.**

**Potential Expansion of the Comprehensive Primary Care (CPC) Initiative**

To show CMS's commitment to supporting advanced primary care, the Comprehensive Primary Care (CPC) Initiative was launched by CMMI on October 1, 2012. This four-year multi-payer

initiative is a collaboration between public and private health payers to test a payment model consisting of non-visit based, risk-adjusted, per-beneficiary-per-month care management payments and shared savings opportunities. The payment model is designed to support practices in the provision of these five comprehensive primary care functions: 1) Risk-Stratified Care Management; 2) Access and Continuity; 3) Planned Care for Chronic Conditions and Preventive Care; 4) Patient and Caregiver Engagement; and 5) Coordination of Care across the Medical Neighborhood. Participating practices in the seven states or regions must demonstrate progress by meeting nine annual Milestones: 1) budget; 2) care management for high risk patients; 3) access and continuity; 4) patient experience; 5) quality improvement; 6) care coordination across the medical neighborhood; 7) shared decision-making; 8) participate in learning collaborative; and 9) health information technology.

**CMS is seeking public comments about issues surrounding a potential expansion of the CPC initiative.** The Agency would use additional rulemaking in the future if CMS decides to expand the CPC initiative. Areas that the Agency has identified for potential issues in the expansion are:

- Practice readiness;
- Practice standards and reporting;
- Practice groupings;
- Interaction with state primary care transformation initiatives;
- Learning activities;
- Payer and self-insured employer readiness;
- Medicaid participation;
- Quality reporting;
- Interaction with the CCM fee; and
- Provision of data feedback to practices.

**Medicare Shared Savings Program**

Proposed New Quality Measure

CMS proposes to add only one new quality measure under the 2016 proposed rule, increasing the number of measures from 33 to 34. The proposed measure, Statin Therapy for the Prevention and Treatment of Cardiovascular Disease, would be added to the Preventive Health domain. The measure was developed by CMS in collaboration with other federal agencies and the Million Hearts® Initiative and is intended to support the prevention and treatment of cardiovascular disease by measuring the use of statin therapies according to the updated clinical guidelines for patients with high cholesterol. 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 one of three different patient categories. **CMS is seeking public comment on the implementation of the measure for the Shared Savings Program with particular reference to whether to consider it as one or three measures as well as benchmarking considerations.**

Proposed Policy for Measures No Longer Aligning With Clinical Guidelines, High Quality Care or Outdated Measures that May Cause Patient Harm

CMS is proposing to add a new provision to reserve the right to maintain a measure as pay-for-reporting, or revert a pay-for-performance measure to pay-for-reporting, if a measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or clinical evidence suggests that continued application of the measure may result in harm to patients. This flexibility will enable CMS to respond more quickly to clinical guideline updates that affect measures without waiting, as currently is required, for a future rulemaking cycle to retire a measure or revert to pay for reporting.

Request for Comment Related to Use of Health Information Technology

CMS is not proposing any changes to the current Health Information Technology (IT) measure "Percent of PCPs Who Successfully Meet Meaningful Use Requirements" (ACO-11) at this time. Through this proposed rule, CMS is seeking comment on how this measure might evolve in the future to ensure that the agency is incentivizing and rewarding EPs for continuing to adopt and use more advanced health IT functionality and broadening the set of EPs across the care continuum that have adopted these tools. **They are specifically seeking comment of the following questions:**

1. Although the current measure focuses only on primary care physicians, should this measure be expanded in the future to include all EPs, including specialists?
2. How could the current measure be updated to reward EPs who have achieved higher levels of health IT adoption?
3. Should CMS substitute or add another measure that would focus specifically on the use of health information technology, rather than meeting overall Meaningful Use requirements? For instance, the transitions of care measure required for the EHR Incentive Program.
4. What other measures of IT-enabled processes would be most relevant to participants within ACOs? How could the Agency seek to minimize the administrative burden on EPs in collecting these measures?

Minor Technical Changes Regarding PQRS Reporting and Beneficiary Attribution

The proposed rule includes minor technical/methodological changes to further align the MSSP program with PQRS reporting and to address attribution issues related to SNF services and Electing Teaching Amendment (ETA) hospitals (hospitals that elect to receive payment on a reasonable cost basis for physician-provided services rather than through the Medicare PFS).

**Value-Based Payment Modifier and Physician Feedback Program**

Continuing its policy established in the final rule for 2015, CMS proposes to continue to apply the value-based payment modifier (VM) to all physicians based on performance data from payment year 2016. Quality reporting data for performance year 2016 will be used to calculate each EP or group practice's VM for payment adjustment year 2018. In addition to applying the VM in 2018 to all physicians, CMS proposes to expand the group of EPs subject to the VM in 2018 to include physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in addition to all physicians.

CMS proposes to use CY 2016 as the performance period for the CY 2018 VM, consistent with policy in previous years. This would be the final performance period under the current VM and PQRS structures, as the first performance period for both tracks created by MACRA would be CY 2017. CMS proposes to continue to include all PQRS GPRO and PQRS individual reporting mechanisms in the VM for payment adjustment year 2018. All of the quality measures that are available to be reported would be used to calculate a group or solo EP's VM to the extent that data on these measures are submitted. Additionally, CMS proposes to not recalculate the VM upward payment adjustment factor after it is made public unless there was a significant error made in the calculation of the adjustment factor.

For the CY 2018 payment adjustment period, CMS proposes to apply the VM to non-physician EPs who are PAs, NPs, CNSs, and CRNAs in groups and those who are solo clinicians and not to other types of clinicians who are non-physicians since they are not included in the initial performance years under MACRA. The Agency proposes to identify TINs as those that consist of non-physician EPs if either the PECOS-generated list or CMS' analysis of the claims data shows that the TIN consists of non-physician EPs and no physicians. CMS would not apply the VM to groups and solo clinicians if either the PECOS-generated list or claims analysis shows that the groups and solo clinicians consist only of non-physician EPs who are not PAs, NPs, CNSs, and CRNAs.

Beginning with the 2016 VM payment adjustment period (which is based off of CY 2014 quality reporting data), CMS proposes to determine the size of a group practice (by TIN) based on the lower of the: 1.) number of EPs indicated by the Medicare Provider Enrollment, Chain, and Ownership System (PECOS)-generated list; or 2.) CMS analysis of the claims data for the purposes of determining the VM payment adjustment amount. Additionally, CMS proposes that a solo EP or group subject to the VM would receive an average quality composite score if the solo/group does not have at least one quality measure that meets the minimum number of cases required for the measure to be included in the quality composite calculation.

CMS proposes to continue to use a two category approach for the CY 2018 VM based on participation in PQRS by groups and solo EPs during performance year 2016, as outlined below.

*Category 1:*

- Solo EPs that meet the criteria to avoid the PQRS payment adjustment;
- Groups that meet the criteria to avoid the PQRS payment adjustment as a group practice participating in PQRS GPRO; and
- Groups that have at least 50 percent of the EPs meet the criteria to avoid the PQRS payment adjustment as individuals, regardless of whether the group registers for PQRS GPRO. In previous years, this option was only available to groups that did not register to participate in PQRS GPRO. If technically feasible, CMS proposes to extend this this policy to the 2017 VM as well.

*Category 2:* groups and solo EPs that are subject to the 2018 VM and do not fall in category 1 (e.g., those that do not meet the PQRS satisfactory reporting/participation criteria).

Consistent with policy for the previous year, CMS proposes to apply to category 2 EPs (i.e., non-PQRS reporters) an automatic 4.0 percent downward payment adjustment VM to groups of 10 or more EPs and a 2.0 percent downward adjustment VM for solo EPs and groups of 2-9 for payment adjustment year 2018. These VM payment adjustments would be in addition to the 2.0 percent downward payment adjustment for failing to satisfactorily report PQRS data for payment adjustment year 2018 (performance year 2016).

CMS proposes to apply the quality-tiering methodology to groups and solo EPs in category 1 (see also tables below). For the CY 2018 VM (based on performance in CY 2016), solo EPs and groups in category one could receive a maximum upward adjustment under the quality-tiering methodology for the CY 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 an adjustment factor for groups with between 2 to 9 EPs and physician solo EPs; and +2.0 times an adjustment factor for groups and solo EPs that consist of non-physician EPs who are PAs, NPs, CNSs, and CRNAs. The amount of payment at risk under the CY 2018 VM to 4.0 percent for groups with 10 or more EPs, 2.0 percent for groups with between 2 to 9 EPs and physician solo EPs, and 0 percent for groups and solo clinicians that consist only of non-physician EPs who are PAs, NPs, CNSs, and CRNAs.

Non-physician EPs who bill under the same TIN as one or more physicians will be subject to the same VM as the physicians in the group practice (same amount of payment at risk and quality-tiering policies). Solo non-physician EPs and group practices that consist only of non-physician EPs (PAs, NPs, CNSs, and CRNAs) will be held harmless from the downward adjustments under the quality-tiering methodology for VM payment adjustment year 2018.

Beginning with the CY 2016 payment adjustment period, a TIN's size would be determined based on the lower of the number of EPs indicated by the PECOS-generated list or CMS' analysis of the claims data for purposes of determining the payment adjustment amount under the VM.

| *CY 2018 –Value Modifier Quality-Tiering Methodology*<br>*Groups with 10 or More EPs (Physicians, PAs, NPs, CNSs, and CRNAs)* | | | |
|---|---|---|---|
| ***Cost/Quality*** | ***Low Quality*** | ***Average Quality*** | ***High Quality*** |
| ***Low Cost*** | *+0.0%* | *+2.0x** | *+4.0x** |
| ***Average Cost*** | *-2.0%* | *+0.0%* | *+2.0x** |
| ***High Cost*** | *-4.0%* | *-2.0%* | *+0.0%* |

| *CY 2018 –Value Modifier Quality-Tiering Methodology*<br>*Solo EPs and Groups of 2-9 (Physicians, PAs, NPs, CNSs, and CRNAs)* | | | |
|---|---|---|---|
| ***Cost/Quality*** | ***Low Quality*** | ***Average Quality*** | ***High Quality*** |
| ***Low Cost*** | *+0.0%* | *+1.0x** | *+2.0x** |
| ***Average Cost*** | *-1.0%* | *+0.0%* | *+1.0x** |
| ***High Cost*** | *-2.0%* | *-1.0%* | *+0.0%* |

| *CY 2018 –Value Modifier Quality-Tiering Methodology*<br>*Solo and Groups with Only Non-physician EPs (PAs, NPs, CNSs, and CRNAs)* | | | |
|---|---|---|---|
| ***Cost/Quality*** | ***Low Quality*** | ***Average Quality*** | ***High Quality*** |
| ***Low Cost*** | *+0.0%* | *+1.0x** | *+2.0x** |
| ***Average Cost*** | *+0.0%* | *+0.0%* | *+1.0x** |
| ***High Cost*** | *+0.0%* | *+0.0%* | *+0.0%* |

** Risk-adjusted for high-risk beneficiaries – Groups and solo EPs are eligible for an additional 1.0x if average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor*

Policies Related to ACOs, CPCi, and other Innovation Center Models

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

- To apply the VM adjustment percentage for groups and solo EPs that participate in two or more ACOs during the applicable performance period based on the performance of the ACO with the highest quality composite score. This is only applicable to ACOs under the Medicare Shared Savings Program.
- To apply an additional upward payment adjustment of +1.0x to Shared Savings ACO Program participant TINs that are classified as "high quality" under the quality-tiering methodology, if the ACOs in which the TINs participated during the performance period have an attributed patient population that has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide as determined under the VM methodology.
- To waive application of the VM for groups and solo EPs, 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, CPC Initiative, or other similar Innovation Center models during the performance period (e.g., Next Generation ACOs, Oncology Care Model, Comprehensive ESRD Care Initiative).

For the CY 2018 payment adjustment period, CMS proposes:

- To apply the VM for groups and solo EPs who participate in an ACO under the Shared Savings Program during the applicable performance period, regardless of whether any EPs in the group or the solo EP also participated in an Innovation Center model during the performance period.
- If the ACO does not successfully report quality data as required by the Shared Savings Program, all groups and solo EPs participating in the ACO will fall in Category 2 for the VM and will be subject to a downward payment adjustment.
- To include CAHPS Surveys in the VM for Shared Savings Program ACOs.

CMS proposes to modify its benchmarking policy to separately benchmark the PQRS electronic clinical quality measures (eCQMs) beginning with the CY 2018 VM. CMS notes that there are several factors that differentiate eCQMs from other equivalent PQRS measures including the

inclusion of all-payer data for eCQMs and the different annual update cycle. This proposed change would be made beginning with the CY 2016 performance period, for which the eCQM benchmarks would be calculated based on CY 2015 performance data.

CMS plans to disseminate QRURs during the fall of 2015 that contain CY 2014 data to all groups and solo EPs that show all TINs their performance during 2014 on all of the quality and cost measures that will be used to calculate the CY 2016 VM. The informal review submission period will occur during the 60 days following release of the QRURs for the 2016 VM and subsequent years. These QRURs will provide data on a group's or solo EP's performance on PQRS quality measures as well as the three claims-based outcome measures calculated for the FM. The reports will accommodate new PQRS reporting options including QCDRs and CAHPS for PQRS. Cost measures in the 2014 QRUR are payment-standardized and risk-adjusted as well as specialty-adjusted to reflect the mix of physician specialties in a TIN. Beginning in Spring 2016, CMS plans to extend dissemination of the mid-year QRURs to non-physician EPs, solo EPs, and groups composed of non-physician EPs. CMS invites feedback on which aspects of the QRURs have been most useful and how the Agency can improve access and actionability of performance reports.

The Agency 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 quality measures as individuals for the relevant CY PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS QCDR for the relevant CY PQRS payment adjustment. Additionally, if the group was initially classified as Category 2, then CMS will likely not have data for calculating the quality composite, in which case the individual/group would be classified as "average quality." However, if the data is available in a timely manner, then CMS proposes to recalculate the quality composite.

CMS uses a minimum episode count for the Medicare Spending per Beneficiary (MSPB) measure for inclusion in a TIN's cost composite. In previous years, the Agency used a 20 episode case minimum that was non-specialty adjusted. However, based on more recent analysis CMS has found this to have lower reliability when specialty adjusted. Therefore, CMS proposes to increase the minimum to 100 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period. The Agency notes that this may create a situation in which a group that would have performed well on this measure will no longer have it included in its cost composite, which could negatively impact their cost composite and ultimately their VM adjustment. CMS also considered a 75 episode minimum rather than 100 and is seeking comments on both alternatives.

CMS also seeks comment on, but makes no proposals regarding, stratifying cost measure benchmarks by beneficiary risk score. The Agency notes that stakeholders have suggested that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries. CMS is considering an option in which cost measure benchmarks would be stratified so that groups and solo EPs are compared to other

groups and individuals treating beneficiaries with similar risk profiles. In this way, within a given grouping (e.g., a quartile or decile), there remains an opportunity to gain efficiencies in care and lower costs, while beneficiary severity of illness and practice characteristics may be more fully recognized at a smaller, and likely less heterogeneous, attributed beneficiary level.

**Physician Self-Referral Updates**

The rule proposes new exceptions and clarifications to the physician self-referral laws, which (1) prohibit 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, unless the requirements of an applicable exception are satisfied; and (2) the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral. Under the rule:

- CMS proposes to add a new exception to permit remuneration from a hospital, FQHC, or RHC to assist a physician or physician practice in employing non-physician clinicians (i.e., physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives) for the purpose of delivering primary care services. This proposed exception recognizes the importance of a robust primary care workforce, the evolving nature of healthcare delivery, and the projected rise in the demand for primary care services resulting from legislation (e.g., Affordable Care Act) and demographic factors.
- CMS proposes to add a new exception that would protect timeshare arrangements for the use of office space, equipment, personnel, supplies, and other services used predominately for the provision of evaluation and management services and that meet certain additional criteria. This proposal would help ensure beneficiary access to care, particularly in rural and underserved areas.
- CMS proposes a number of highly technical definitional and requirement clarifications related to such issues as physician-owned hospitals, the protocol to self-disclose violations of the self-referral regulations (and consequently reduce potential penalties), and compensation relationships.
- CMS, recognizing the evolving healthcare system, is requesting comment from stakeholders on changes that may need to be made to the self-referral laws so that they do not inappropriately restrict the financial relationships necessary to achieve the clinical and financial integration required for successful value-based health care delivery and payment reform.

**Private Contracting/Opt-out**

The rule proposes regulatory changes to conform to a provision contained within the recently passed MACRA. Clinicians who do not wish to enroll in the Medicare program may "opt-out" of Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. The clinician also must submit an affidavit to Medicare expressing his/her decision to opt-out of the program. Prior to the passage of MACRA, the statute indicated that the longest interval for which a Medicare opt-out affidavit from a clinician can be effective is two years. Continued opt-out after this interval required a renewed affidavit. MACRA changed the statute to

automatically renew the opt-out affidavits every two years. Clinicians are able to rescind their opt-out status if they notify CMS at least 30 days prior to the start of the next two-year period.