

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

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### Regulatory Impact Analysis

In this final rule, to maintain budget neutrality for the finalized policies, the 2016 conversion factor (CF) will be \$35.8279. The impact for internal medicine with this CF for the year 2016 is 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:

<b>Specialty</b>	<b>Allowed charges (mil)</b>	<b>Impact of work RVU changes %</b>	<b>Impact of PE RVU changes %</b>	<b>Impact of MP RVU changes %</b>	<b>Combined Impact ** %</b>
(A)	(B)	(C)	(D)	(E)	(F)
<i>** Column F may not equal the sum of columns C, D, and E due to rounding.</i>					
TOTAL	\$89,020	0	0	0	0
Allergy/Immunology	221	0	0	0	0
Cardiology	6,498	0	0	0	0
Critical Care	296	0	0	0	0
Endocrinology	454	0	0	0	0
Gastroenterology	1,843	-2	-1	-1	-4
Geriatrics	216	0	0	0	0
Hematology/Oncology	1,788	0	0	0	0
Infectious Disease	660	0	0	0	0
Internal Medicine	11,058	0	0	0	0
Nephrology	2,199	0	0	0	0
Neurology	1,524	0	-1	0	-1

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	1,780	0	0	0	0
Rheumatology	536	0	0	0	0

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

For calendar year (CY) 2016, the Centers for Medicare and Medicaid Services (CMS) finalized the crosswalk as proposed to use a proxy practice expense per hour (PE/HR) value for interventional cardiology by crosswalking the PE/HR from Cardiology. The change is reflected in the “PE/HR” file available on the CMS website under the supporting data files for the CY 2016 PFS final rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>.

CMS finalized modifications to two steps in the Calculating the Direct Cost PE RVUs methodology. For Step 2, CMS will calculate the aggregate pool of direct PE costs for the current year. CMS finalized the proposal 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 modification will result in greater stability in the relationship between the work and PE RVU components in the aggregate. It is not anticipated to affect the distribution of PE RVUs across specialties. CMS finalized this refinement and the PE RVUs in this final rule reflect this change to the PE methodology.

For Step 7 of the PE methodology, CMS finalized the proposal 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. Using an average of the three most recent years of available data may increase stability of PE RVUs and mitigate code-level fluctuations for both the full range of PFS codes, and for new and low-volume codes.

CMS believes that the 3-year average of available Medicare claims data will mitigate the need to use dominant or expected specialty instead of the claims data. It is also stated by CMS that this hypothesis will be tested as soon as a new year of claims data is incorporated into the PFS ratesetting methodology. It is anticipated that CMS will incorporate CY 2015 claims data for use in CY 2017 ratesetting and that the proposed PE RVUs associated with the CY 2017 PFS proposed rule will provide the best opportunity to determine whether service-level overrides of claims data are necessary. Therefore, CMS finalized the policy as proposed for CY 2016 but will

seek comment on the proposed CY 2017 PFS rates and whether or not the incorporation of a new year of utilization data mitigates the need for service-level overrides. CMS will also reconsider whether or not to use a claims-based approach (dominant specialty) or stakeholder-recommended approach (expected specialty) in the development of PE RVUs for low-volume codes.

#### 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 Picture Archiving and Communication System (PACS) workstation as a direct expense. CMS has proposed to update the price for the PACS workstation to \$5,557 from the current price of \$2,501 since the latter price was based on the proxy item and the former based on submitted invoices. Comments were solicited as to whether it may be appropriate to include these costs as direct inputs for the associated Healthcare Common Procedure Coding System (HCPCS) codes, given that many of these services are reported globally in the non-facility setting. These costs will be incorporated into the PE RVUs of the global and technical component of the HCPCS code. CMS has decided to finalize the proposal to update the price for the PACS workstation to \$5,557.

Input from stakeholders, including the Relative Value Scale Update Committee (RUC), was requested to determine whether or not the PACS workstation used in imaging codes is the same workstation that is used in the post processing described by Current Procedural Terminology (CPT) code 76377 or if a more specific workstation should be incorporated in the direct PE input database. Based on the comments received, CMS agrees that the “computer workstation, 3D reconstruction CT-MR” equipment (ED014) should be restored to the equipment list and assigned to CPT code 76377 with an equipment time of 38 minutes. However, CMS does not believe that the typical service for CPT code 76377 will also use the PACS workstation. Therefore, CMS substituted ED014 in place of the PACS workstation.

#### Standardization of Clinical Labor Tasks

CMS finalized standard times for clinical labor tasks associated with digital imaging at two minutes for “Availability of prior images confirmed;” two minutes for “Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist;” two minutes for “Review examination with interpreting MD;” and one minute for “Exam documents scanned into PACS, Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.” However, CMS did not finalize a standard time for clinical labor task “Technologist QC’s images in PACS, checking for all images, reformats, and dose page” at this time, pending consideration of any additional public comment and future rulemaking.

The Agency corrected inconsistencies with CPT codes 22510 (Percutaneous vertebroplasty; cervicothoracic), 22511 (Percutaneous vertebroplasty; lumbosacral), and 22514 (Percutaneous vertebral augmentation; lumbar) in the CY 2016 proposed direct PE input database to reflect the RUC recommended values, without refinement.

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

For CY 2016, CMS continued the current approach for determining malpractice (MP) RVUs for new/revised codes. For CY 2016, the Agency finalized the proposal to begin conducting annual Malpractice (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 will continue to be updated every five years using updated premium data but will remain unchanged between the five-year reviews.

Beginning in CY 2016 CMS will perform annual MP RVU updates to:

- Reflect changes in the mix of clinicians providing services;
- Adjust MP RVUs for risk; and
- Modify the specialty mix assignment methodology to use an average of the three most recent years of available data instead of a single year.

It was noted that CMS will continue to maintain the code-specific overrides where the claims data are inconsistent with a specialty that will reasonably be expected to furnish the services.

CMS will also begin performing an additional refinement in the process for assigning MP RVUs to individual codes. After examining the calculation of MP RVUs, CMS does not believe that this floor should apply to add-on codes. Since add-on codes must be reported with another code, there is already an MP floor of 0.01 that applies to the base code, and therefore, to each individual service. By applying the floor to add-on codes, the current methodology practically creates a 0.02 floor for any service reported with one add-on code and 0.03 for those with two add-on codes, etc. Therefore, CMS proposed to maintain the 0.01 MP RVU floor for all nationally-priced PFS services that are described by base codes, but not for add-on codes. CMS will continue to calculate, display, and make payments that include MP RVUs for add-on codes that are calculated to 0.01 or greater, including those that round to 0.01. CMS only proposed to allow the MP RVUs for add-on codes to round to 0.00 where the calculated MP RVU is less than 0.005.

After receiving many comments to increase the transparency regarding the list of services with MP RVU overrides, CMS posted a public use file containing the overrides. The file is available on the CMS Web site under the supporting data files for the CY 2016 PFS final rule at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSchd/index.html>.

### **MP RVU Update for Anesthesia Services**

For CY 2016 CMS finalized the policy as 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.

### MP RVU Methodology Refinements

To address an identified necessary refinement in computing a preliminary national average premium for each specialty and increase stability of MP RVUs, CMS finalized its proposal to update the calculation to use a price-adjusted premium (that is, the premium divided by the geographic practice cost index (GPCI)) in each and then take a weighted average of those adjusted premiums. The CY 2016 PFS 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.” 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 less than \$10 million in allowed charges, and those that describe anesthesia or Evaluation and Management (E/M) services.

Although a number of codes have been or will be considered through the RUC review process, until CMS receives recommendations and reviews the codes for both work and direct PE inputs, CMS will continue to include these codes on the high expenditure list. CMS states “we do not believe that the presence of a code on a potentially misvalued code list signals that a particular code necessarily is misvalued. Instead, the lists are intended to prioritize codes to be reviewed under the misvalued code initiative.” Accordingly, CMS finalized 103 codes as potentially misvalued services under the high expenditure screen and seeks recommended values for these codes from the RUC and other interested stakeholders.

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

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 continues to seek 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. Through notice and comment rulemaking, CMS will continue to review and consider any recommendations from the public, including those from any interested specialty societies.

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, it was 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 identified CPT codes 00740 and 00810 as potentially misvalued. CMS will continue to consider input from the medical community on this issue through evaluation of CPT coding changes and associated RUC recommendations, as well as feedback received through public comments, as they value these services through future notice and comment rulemaking.

#### Improving the Valuation and Coding of the Global Package

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 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 solicited comments 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 also sought 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 received supportive comments of the need to identify auditable, objective, representative data, such comments as:

- Collect and examine large group practice data for CPT code 99024 (post-operative follow-up visit).
- Review Medicare Part A claims data to determine the length of stay of surgical services performed in the hospital facility setting.
- Prioritize services that the Agency has identified as high concern subjects.

- Review postoperative visit and length of stay data for outliers. However, many commenters were not able to identify a specific source for such data.

CMS will however, consider the suggestions they received for purposes of future rulemaking.

CMS received many comments regarding potential methods of valuing the individual components of the global surgical package, including the following:

- Use a measured approach to valuing the individual components of the global surgical package rather than implementing a blanket data collection policy.
- Examine and consider the level of the post-operative E/M visits, including differences between specialties.
- Consider the interaction between the valuing the global surgery package and the multiple procedure payment reduction (MPPR) policy.

The Agency will consider these comments regarding the best means to develop and implement the process to gather information needed to value surgical services and will provide further opportunity for public comment through future rulemaking.

#### **Refinement Panel**

The Agency will retain the ability to convene refinement panels for codes with interim final values under circumstances where additional input provided by the panel is likely to add value as a supplement to notice and comment rulemaking. The Agency will make the determination on whether to convene refinement panels on an annual basis, based on review of comments received on interim final values.

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

The Agency continues to be interested in receiving comments for future rulemaking 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.

CMS anticipates using a multi-year approach as it considers ways to recognize different resources (particularly in cognitive work), to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting. The Agency will take the comments it has received into consideration in developing any potential policy proposals in future PFS rulemaking.

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 - 99495-99496)

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 - 99490) 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 was sought on how best to balance access to TCM and CCM services and the administrative burden for clinicians who provide these services.

### Chronic Care Management (CCM)

In the proposed rule, CMS requested information regarding the circumstances under which the CCM code is provided, the range of minutes per month, and objective data regarding the resource costs associated with providing the service.

CMS stated that they received comments on the CCM code from various stakeholders, such as:

- The current payment amounts are not adequate to cover the resources required to furnish CCM services, with a call for CMS to increase payments, for example, by:
  - Creating an add-on code to CPT code 99490;
  - Increasing the clinical labor PE input for CPT code 99490 to the RUC recommended 60 minutes; and/or
  - Paying separately for the complex CCM codes (CPT codes 99487 and 99489).
- Reducing the administrative burden for CCM by:
  - Eliminating the requirement to use certified electronic health record technology (CEHRT);
  - Suspending the electronic care plan sharing requirement until such time that electronic health records (EHRs) have the ability to support such capabilities;
  - Having CMS provide a model patient consent form; and
  - Clarifying the application of CCM rules regarding fax transmission from certified EHRs.

In CY 2016 no changes are made to CCM. However, the Agency stated that "CMS will develop subregulatory guidance clarifying the intersection of fax transmission and CEHRT for purposes of CCM billing." The Agency also stated "as they review the information received regarding the resource costs associated with furnishing CCM services, in addition to their own claims data, CMS will consider any changes in payment and coding that may be warranted in the coming years, including the possibility of establishing separate payment amounts and making Medicare payment for the related CPT codes, such as the complex care coordination codes, CPT codes 99487 and 99489.

### Transitional Care Management

Regarding TCM service, CMS is adopting the suggestions that the required date of service reported on the claim be the date of the face-to-face visit and submission of the claim when the face-to-face visit is completed be allowed (but not required).

### Collaborative Care

“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 clinician 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 interested in 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 whether the collaborative care model should be implemented through a Center for Medicare and Medicaid Innovation (CMMI) demonstration to most effectively support this model.

The Agency will take all comments into consideration as it considers the development of proposals in future rulemaking. Particular note was given to the identification of resource inputs that CMS might use to value collaborative care services under the PFS, including defined time elements. As the Agency considers those comments, stakeholders are encouraged to consider whether there are alternatives to time elements that would account for the range in intensity of services delivered in accordance with beneficiary need. In addition, since the collaborative care models described in the rule include primary care-based care management, as well as psychiatric consulting, CMS encourages further input including comments on this final rule with comment period, from a broad group of stakeholders, including the community of primary care clinicians, who are critical in the successful provision of these services.

### Target for Relative Value Adjustments for Misvalued Services

The Protecting Access to Medicare Act of 2014 (PAMA), passed 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 proposed 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 will 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 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 outlined a number of potential problems with including these codes in the calculation for the 2016 target and therefore excluded any code value changes for CY 2015 interim values from the calculation of the CY2016 misvalued code target.

Further, CMS used 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.

CMS continues to believe this approach is appropriate and compliant with statutory directives. The Agency finalized the policy as proposed with a modification to exclude from the calculation of the “net reduction” in expenditures changes in coding and valuation for services, such as Advance Care Planning for CY 2016, that are newly reportable, but for which no corresponding reduction is made to existing codes and instead reductions are taken exclusively through a budget neutrality adjustment.

In this rule, CMS has identified changes that achieve 0.23 percent in net reductions. This will require a 0.77 percent reduction to all PFS services payment amounts to meet the 1.0 percent net reduction target, as required by the statute.

#### **Phase-in of Significant RVU Reductions**

The Protecting Access to Medicare Act (PAMA) specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would 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 Achieving a Better Life Experience (ABLE) Act accelerated the phase-in to begin in CY 2016.

In this final rule for CY 2016, CMS is implementing the phase-in for significant (20 percent or greater) reductions in RVUs. The Agency is also finalizing policy to identify significant reductions in RVUs based on a comparison of RVUs before application of budget neutrality adjustment

along with the policy to phase in 19 percent of the reduction in value in the first year, and the remainder of the reduction in the second year.

CMS finalized the proposal 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 will 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.

The list of codes subject to the phase-in and the associated RVUs that result from this methodology are available on the CMS website under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

### **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.

This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2016, with the label “CT,” and the long descriptor “Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard.” Beginning January 1, 2016, hospitals and suppliers will be required to report the modifier “CT” on claims for CT scans described by any of the CPT codes identified above (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scanners. The use of this modifier will result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

### **Valuation of Specific Codes**

#### **Misvalued Code Changes for Lower GI Endoscopy Services**

In the CY 2015 PFS final rule, CMS delayed valuing the lower GI codes indicating the Agency would propose values for these codes in the CY 2016 proposed rule. CMS cited the new process for including proposed values for new, revised and potentially misvalued codes in the proposed rule as one of the reasons for the delay.

The AMA Current Procedural Terminology (CPT) Editorial Panel revised the lower gastrointestinal endoscopy code set for CY 2015 following identification of some of the codes as

potentially misvalued. The RUC subsequently provided recommendations to CMS for valuing these services. For 2016, CMS is finalizing implementation of the revised set of codes, including the revised values. CMS is finalizing payment rates more closely tied to the RUC recommended values (a list of Relative Value Units and Related Information Used in CY 2016 Final Rule can be found at the following link: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-FC.html> ). These new values are reflected in the specialty impact table and reveal the gastroenterologist specialty impact (in the earlier table) is more significant than for other IM specialties.

### 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)).

In this final rule for CY 2016, CMS decided to adopt the CPT codes 99497 and 99498 as payable under the Medicare PFS beginning on January 1, 2016. The Advance Care Planning codes 99497 and 99498 are assigned status indicator “A,” which is defined as: “Active code” and are separately payable. The RUC-recommended values for these CPT codes were accepted by CMS. The work RVU for 99497 is 2.40 with an estimated payment of \$85.99 and the work RVU for 99498 is 2.09 with an estimated payment of \$74.88.

Medicare has not made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy. However, by including Advance Care Planning services as an optional element of the Annual Wellness Visit (AWV) (for both the first visit and subsequent visits), this rule creates an annual opportunity for beneficiaries to access ACP services should they elect to do so.

When Advance Care Planning is provided at the same time as the Annual Wellness Visit (AWV), Advance Care Planning should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV. When a patient elects to receive Advance Care Planning services, cost sharing will apply as it does for other physicians’ services except when Advance Care Planning is provided as part of the AWV.

Advance Care Planning could be paid on the same day or a different day as other E/M services. It may also be used during the same service period as TCM or CCM services and within global surgical periods. This is a physician service; therefore, “incident to” rules apply when these services are furnished incident to the services of the billing clinician, including a minimum of direct supervision.

### **Medicare Telehealth Services**

CMS will add the following codes to the list of Medicare telehealth services beginning in CY 2016 on a category 1 basis: Prolonged service inpatient CPT codes 99356 and 99357 and ESRD-related services 90963 through 90966. The prolonged service codes can only be billed in conjunction with subsequent hospital and subsequent nursing facility codes. Limits of one subsequent hospital visit every three days, and one subsequent nursing facility visit every 30 days, will continue to apply when the services are furnished as telehealth services. For the ESRD-related services, the required clinical examination of the catheter access site must be furnished face-to-face “hands on” (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA.

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

CMS amended the regulations regarding “incident to” services 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 (OIG) or who have had their enrollment revoked for any reason.

CMS also made a revision to reflect the Agency’s policy that the physician (or other clinician) supervising the auxiliary personnel need not be the same physician (or other clinician) treating the patient more broadly. In addition to this revision, the Agency will add clarifying regulation text specifying that only the physician or other practitioner under whose supervision the incident to service(s) is being provided is permitted to bill the Medicare program for the incident to services.

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

The subregulatory guidance in the Medicare Claims Processing Manual will be updated (Pub. 100-4, Chapter 13, Section 90.3) to clarify the portable X-ray transportation fee proration policy, effective January 1, 2016. It is believed that the revision to the Manual will provide consistent direction to all MACs in the payment of portable X-ray transportation for Medicare Part B claims. In addition, CMS believes the revision strengthens program integrity under Medicare Part B because Medicare will no longer pay for more than its share of the portable X-ray transportation costs.

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

CMS finalized its proposal to 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 policy will 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. This final rule allows for an additional payment for the costs of CCM services that are not already captured in the RHC AIR or the FQHC PPS payments beginning on January 1, 2016. The requirements of CCM services 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 will 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 will be applied as applicable to FQHC claims, and coinsurance and deductibles will 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 proposed 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 proposed 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:

<b>Title of Proposed Definition or Process</b>	<b>Proposed Definition or Process</b>
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 Appropriate Use Criteria	AUC developed, modified, or endorsed by a qualified provider-led entity.
Required Process for Qualified Provider-led Entities for the Development of an AUC	<p>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.</p> <p>(1) Requirements for developing, modifying or endorsing AUC. All of the following must be met:</p> <p>(i) An evidentiary review process that includes:</p> <ul style="list-style-type: none"> <li>(A) A systematic literature review of the clinical topic and relevant imaging studies; and</li> <li>(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.</li> </ul> <p>(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.</p> <p>(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:</p> <ul style="list-style-type: none"> <li>(A) Direct or indirect financial relationships that exist between</li> </ul>

	<p>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.</p> <p>(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 organizations that may financially benefit from the AUC.</p> <p>(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.</p> <p>(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.</p> <p>(vi) The provider-led entity must have a transparent process for the timely and continual updating of each criterion.</p> <p>(vii) The provider-led entity’s process for developing, modifying or endorsing AUC is publicly posted on the entity’s website.</p>
<p>Process to Identify Qualifying Provider-led Entities</p>	<p>Provider-led entities must meet all of the following criteria:</p> <p>(i) Provider-led entities must submit an application to CMS that documents adherence to each of the AUC development requirements outlined in this section;</p> <p>(ii) Applications will be accepted by CMS only from provider-led entities that meet the definition in this section;</p> <p>(iii) Applications must be received by CMS annually by January 1;</p> <p>(iv) All approved provider-led entities from each year of submissions will be posted to the CMS website by June 30; and</p> <p>(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.</p>
<p>Process to Identify Priority Clinical Areas</p>	<p>(1) CMS must identify priority clinical areas through annual rulemaking and in consultation with stakeholders.</p> <p>(2) CMS will consider incidence and prevalence of disease, volume variability of utilization, and strength of evidence for imaging services.</p>

	<p>CMS will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.</p> <p>(3) The Medicare Evidence Development &amp; Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.</p> <p>(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals as defined in the statute.</p>
<p>Process to Identify Non-evidence Based AUC</p>	<p>(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.</p> <p>(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.</p>

Most aspects of these policies were finalized as they were proposed in the CY 2016 PFS proposed rule, however, CMS made the following changes.

CMS is implementing the first component of this program in this PFS final rule with comment period by establishing which organizations are eligible to develop or endorse appropriate use criteria, the evidence-based requirements for AUC development and the process CMS will follow for qualifying provider-led entities (PLEs).

Regarding the role of endorsement of AUC, CMS will add a new section §414.94(d) to the regulations. This new section will clearly describe the role of endorsement. In this new section it is noted that only a qualified PLE may provide endorsement of AUC. Further, qualified PLEs may only endorse the AUC of other qualified PLEs. Independently, each organization must have been qualified, and therefore, participation by CMS in the endorsement relationship is not envisioned. The primary function of endorsement is for qualified PLEs to combine their AUC to create a larger, more clinically encompassing library.

This final rule provides clarification around what is expected regarding a systematic literature review. The evidence review requirement does not mean that PLEs must commission external systematic evidence reviews or technology assessments. It is expected many organizations will undertake their own systematic evidence review to ensure all relevant evidence-based information is considered and evaluated. The literature review must be systematic, reproducible and encompass all relevant literature related to the specific imaging study. Ideally, the review will include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the PLE must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. CMS does not require that a particular methodology be used as there may be certain methodologies better suited to some evidentiary assessments than others.

CMS will post information on our website for this program accessible at:  
<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>.

**Physician Compare Website**

This section of the 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 did not finalize the proposal 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). CMS noted that because the VM as a standalone adjustment will end after CY 2018 (based on performance year 2016) due to implementation of MACRA, including the VM indicator for such a short period of time may be confusing to consumers since it will be replaced by a an indicator related to Merit-based Incentive Payment System (MIPS) in future years.

In 2015, an indicator was included if EPs satisfactorily reported four individual PQRS cardiovascular prevention measures. CMS now will also include an indicator for EPs who satisfactorily report on the newly finalized Cardiovascular Prevention measures group under PQRS.

CMS will 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).

The Agency will also 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). CMS finalized its proposal 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. Each QCDR will 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 Final Measure and Participation Data for Public Reporting**

<b>Data Collection Year</b>	<b>Data Publication Year</b>	<b>Data Type</b>	<b>Reporting Mechanism</b>	<b>Proposed Quality Measures and Data for Public Reporting</b>
2016	2017	PQRS, PQRS	Web Interface,	Include an indicator for satisfactory reporters under PQRS,

<b>Data Collection Year</b>	<b>Data Publication Year</b>	<b>Data Type</b>	<b>Reporting Mechanism</b>	<b>Proposed Quality Measures and Data for Public Reporting</b>
		GPRO, EHR, and Million Hearts	EHR, Registry, Claims	participants in the EHR Incentive Program, and EPs who satisfactorily report the Cardiovascular Prevention measures group under PQRS in support of Million Hearts.
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.  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.  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 GPRO	Web Interface, EHR, Registry,	The following data for group practices and individual EPs in the downloadable database:

Data Collection Year	Data Publication Year	Data Type	Reporting Mechanism	Proposed Quality Measures and Data for Public Reporting
			Claims	<ul style="list-style-type: none"> <li>• 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.</li> <li>• A notation of the payment adjustment received based on the cost and quality tiers.</li> <li>• An indication if the individual EP or group practice was eligible to but did not report quality measures to CMS.</li> </ul>

**New Benchmarking Methodology**

CMS finalized the proposal to report publicly on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology<sup>1</sup> annually based on the PQRS performance rates most recently available (i.e., in 2017 report a benchmark derived from 2016 PQRS performance rates). This will only apply to measures deemed valid and reliable and that are reported by enough EPs or group practices to produce a valid result. ABC™ 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 that data to set a point of comparison for all of those groups or individual EPs who report the measure. CMS also finalized its proposal to use the ABC™ methodology to generate a benchmark that can be used to systematically assign stars for the Physician Compare 5 star rating.

CMS will continue to make available for public reporting all patient experience data from Consumer Assessment of Healthcare Providers and Systems (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.

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<sup>1</sup> Kiefe CI, Weissman NW, Allison JJ, Farmer R, Weaver M, Williams OD. Identifying achievable benchmarks of care: concepts and methodology. International Journal of Quality Health Care. 1998 Oct; 10(5):443-7. <http://intqhc.oxfordjournals.org/content/10/5/443>.

The rule finalizes the proposal 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 will also 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 finalized the inclusion utilization data generated from Part B claims on services and procedures provided to Medicare beneficiaries in the downloadable database by HCPCS code. MACRA requires 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 finalized the proposal to add 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. CMS will consider including additional certification boards in future rulemaking based on comments received.

CMS also sought comment on the following additional data elements that the Agency may consider including in future rulemaking:

- The types of quality measure that will help fill gaps and meet the needs of stakeholders and will 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 will 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 Qualified Clinical Data Registries (QCDRs). Beginning in 2016, CMS will also allow QCDRs to submit quality measures data for group practices. The complete requirements for satisfactorily reporting PQRs for each reporting mechanism for performance year 2016 are outlined in the table below.

The Agency did not finalize its proposal to require group practices with 25 -99 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. However, groups with 100 or more EPs that participate in GPRO will be required to collect CAHPS for PQRS data, as was required in 2015. Smaller group practices may voluntarily elect to use the CAHPS for PQRS survey in 2016. 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 will be required to report on at least one measure in the cross-cutting measures set. CMS will 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 will 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**

<b>Group Practice Size</b>	<b>Measure Type</b>	<b>Reporting Mechanism</b>	<b>Satisfactory Reporting/ Participation Criteria</b>
Individual/Solo	Individual Measures	Claims, Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP’s Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the 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

<b>Group Practice Size</b>	<b>Measure Type</b>	<b>Reporting Mechanism</b>	<b>Satisfactory Reporting/ Participation Criteria</b>
			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 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 - 99 EPs  100 + 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,

Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting/ Participation Criteria
			<p>then the group practice must report on 100 percent of assigned beneficiaries. In other words, CMS understands that, in some instances, the sampling methodology provided 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.</p>
<p>25 – 99 EPs that elect CAHPS for PQRS;</p> <p>100 + EPs (if CAHPS for PQRS applies)</p>	<p>Individual GPRO Measures in GPRO Web Interface + CAHPS for PQRS</p>	<p>GPRO Web Interface + CMS-Certified Survey Vendor</p>	<p>The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group’s sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data. 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.</p>

<b>Group Practice Size</b>	<b>Measure Type</b>	<b>Reporting Mechanism</b>	<b>Satisfactory Reporting/ Participation Criteria</b>
2 - 99 EPs;  100 + EPs (if CAHPS for PQRS does not apply)	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 - 99 EPs that Elect CAHPS for PQRS;  100 + EPs (if CAHPS for PQRS applies)	Individual Measures + CAHPS for PQRS	Qualified Registry + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the PQRS cross-cutting measure set.
2 – 99 EPs;	Individual Measures	Direct EHR Product or EHR	Report 9 measures covering at least 3 domains. If the group practice's direct

<b>Group Practice Size</b>	<b>Measure Type</b>	<b>Reporting Mechanism</b>	<b>Satisfactory Reporting/ Participation Criteria</b>
100 + EPs (if CAHPS for PQRs does not apply)		Data Submission Vendor Product	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 - 99 EPs that elect CAHPS for PQRs;  100 + EPs (if CAHPS for PQRs applies)	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-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 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 measure 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 but did not finalize a requirement to collect these data in this final rule.

#### Selection of Quality Measures for 2016 and Beyond

In selecting measures, CMS is required to select measures that have been endorsed by an 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 Social Security Act 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 needs 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 National Quality Strategy (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 finalized the addition of 37 new individual measures to PQRS for the 2016 performance period and the removal of 10 measures. The Agency finalized the addition of four new cross-

cutting measures for PQRS reporting in CY 2016 (in addition to the 19 cross-cutting measures that had been previously finalized):

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

CMS finalized the addition of 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 proposed rule 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. The areas that CMS sought comment on were the determination of a low-volume threshold for excluding EPs from MIPS, activities that should be included in the Clinical Practice Improvement Activities performance category, and APMs. Since the publication of the proposed rule for the PFS, CMS issued a request for information (RFI) containing a number of detailed questions on a much broader range of topics pertaining to MACRA.<sup>2</sup> In this final rule, CMS did not establish any policies related to MACRA but noted that the Agency will consider comments on the both proposed rule and RFI in future rulemaking related to MACRA.

#### **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 finalized the proposal 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 finalized the proposal to revise

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<sup>2</sup> 80 *Federal Register* 59102. Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models. October 1, 2015. Accessed at: <https://www.federalregister.gov/articles/2015/10/01/2015-24906/request-for-information-regarding-implementation-of-the-merit-based-incentive-payment-system>

the CEHRT definition for 2018 and subsequent years to require that EHR technology is certified to report eQMs using the same standards. The CEHRT definition for 2015 through 2017 included in the current Stage 3 rule allows EPs to use 2014 Edition or 2015 Edition certified EHR technology. These policies apply to EPs, eligible hospitals, and CAHs. CMS made 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 eQMs 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 finalized the proposal 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 eQm 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 finalized its proposal 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 through 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

The Agency will 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.

The Agency received supporting comments suggesting matters to consider in a potential future expansion of the CPC initiative including:

- Engagement of electronic health record vendors;
- Coaching on leadership and change management;
- Documentation;
- Beneficiary cost-sharing;
- Care management;
- Further testing of the CPC initiative;
- Eligibility for incentive payments for participation in Alternative Payment Models under MACRA;
- Auditing requirements;
- Aggregation of payer and clinical data; and
- Engagement with providers across the broader medical neighborhood.

These comments, broadly supported CPC expansion. The Agency will consider the comments received when determining if the CPC initiative will be expanded through future rulemaking.

### **Medicare Shared Savings Program**

The Medicare Shared Savings Program was established to promote accountability for a patient population, coordinate items and services under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery through provider and supplier participation in an ACO. The CY 2016 PFS final rule finalizes policies specific to certain sections of the Shared Savings Program regulations including:

- Adding a measure for Statin Therapy for the Prevention and Treatment of Cardiovascular Disease in the Preventive Health domain of the Shared Savings Program quality measure set to align with updated clinical guidelines and PQRS reporting;
- Preserving flexibility to maintain or revert measures to pay for reporting if a measure owner determines the measure no longer aligns with updated clinical practice or causes patient harm;
- Clarifying how PQRS EPs participating within an ACO meet their PQRS reporting requirements when their ACO satisfactorily reports quality measures; and
- Amending the definition of primary care services to include claims submitted by Electing Teaching Amendment hospitals and to exclude certain claims for services furnished in Skilled Nursing Facilities.

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

Continuing its policy established in the final rule for 2015, CMS will 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 finalized expanding 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 finalized the use of CY 2016 as the performance period for the CY 2018 VM, consistent with policy in previous years. This will be the final performance period under the current VM and PQRS structures, as the first performance period for MACRA may begin in CY 2017. CMS will 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 will be used to calculate a group or solo EP's VM to the extent that data on these measures are submitted. Additionally, CMS will 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 finalized the proposal 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 finalized its proposal to identify Taxpayer Identification Numbers (TINs) as those that consist of non-physician EPs if either the Medicare Provider Enrollment, Chain, and Ownership System (PECOS)-generated list or analysis of the claims data shows that the TIN consists of non-physician EPs and no physicians. CMS will 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 finalized the proposal to determine the size of a group practice (by TIN) based on the lower of the: 1.) number of EPs indicated by the PECOS-generated list; or 2.) CMS analysis of the claims data for the purposes of determining the VM payment adjustment amount. Additionally, CMS finalized the proposal that a solo EP or group subject to the VM will 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 will 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. In the final rule, CMS also finalized its proposal to extend this flexibility to group practice reporting for the 2017 VM (based on performance year 2015 PQRS reporting) 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 finalized the proposal 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 are 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 finalized the proposal 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 is 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 will 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.

<i>Groups with 10 or More EPs (Physicians, PAs, NPs, CNSs, and CRNAs)</i>			
<b>Cost/Quality</b>	<b>Low Quality</b>	<b>Average Quality</b>	<b>High Quality</b>
<b>Low Cost</b>	+0.0%	+2.0x*	+4.0x*
<b>Average Cost</b>	-2.0%	+0.0%	+2.0x*
<b>High Cost</b>	-4.0%	-2.0%	+0.0%

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

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

- 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 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.
- 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 finalized the following policies:

- 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 finalized the proposal to modify the 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 change will be made beginning with the CY 2016 performance period, for which the eCQM benchmarks will be calculated based on CY 2015 performance data.

CMS disseminated Quality and Resource Use Reports (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. CMS has established an informal review submission period that 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 VM. The reports 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.

The Agency finalized the proposal 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 are 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 finalized an increase in the minimum to 125 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period.

### **Physician Self-Referral Updates**

Physician self-referral laws (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. The final rule includes new exceptions and clarifications to the self-referral laws as follows:

- The rule establishes a new exception to permit payment by hospitals, Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs) to physicians for the purpose of compensating non-physician clinicians under certain conditions. It also establishes a new exception to permit timeshare arrangements for the use of office space, equipment, personnel, items, supplies, and other services. CMS believes these new exceptions will enhance access to care across all areas and will be particularly helpful in rural and underserved areas.
- The rule formalizes provisions established by the ACA on physician-owned hospitals, including setting a baseline physician ownership percentage that they cannot exceed, defining how this baseline is calculated and requiring these facilities to state on their websites and in their advertising that they are owned by physicians.

### **Private Contracting/Opt-out**

Prior to MACRA, physicians and other clinicians who wished to renew their opt-out status were required to file new, valid affidavits with their Medicare Administrative Contractors (MACs) every two years.

Section 106(a) of MACRA indicates that valid opt-out affidavits filed on or after June 16, 2015, automatically renew every two years. Therefore, physicians and other clinicians who filed valid opt-out affidavits on or after June, 16, 2015, are not required to file renewal affidavits. If physicians and other clinicians who filed affidavits effective on or after June 16, 2015, do not want their opt-out status to automatically renew at the end of a two-year opt-out period, they may cancel the renewal by notifying all MACs with which they filed an affidavit in writing at least 30 days prior to the start of the new two-year opt-out period.

**Conclusion**

The policies in the physician fee schedule have a January 1, 2016, effective date unless otherwise noted. To view a copy of the final rule in its entirety as well as all related materials, go to: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>.