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2016 Medicare Physician Fee Schedule Final Rule Annotated Summary

+Insights

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The final rule goes into effect on January 1, 2016, with comments due by December 29, 2015. This article details the key changes implemented by the ruling.

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The Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (CMS-1631-FC) was published in the *Federal Register* on November 16, 2015. This final rule with comment period updates payment policies and payment rates for services furnished on or after January 1, 2016. The rule also finalizes changes to several of the quality reporting initiatives that are associated with the Medicare Physician Fee Schedule (PFS) payments, including the Physician Quality Reporting System (PQRS), the Physician Value-Based Payment Modifier (Value Modifier) and the Medicare Electronic Health Record (EHR) Incentive Program, as well as changes to the Physician Compare website on Medicare.gov.

This is the first PFS final rule since the repeal of the Sustainable Growth Rate formula by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The 2016 final rule updates the relative value unit (RVU) methodology, a fee-for-service (FFS) – based reimbursement formula for Medicare physician services that has been in place since 1992. Yet through provisions related to the implementation of various physician performance initiatives, such as PQRS and the Value Modifier, it also reflects the broader and forward-looking efforts of the Centers for Medicare and Medicaid Services (CMS) and the Administration to move towards a more value-based healthcare system.

The provisions of this final rule with comment period are effective on January 1, 2016, except when noted. Comments are due by December 29, 2015.

Medicare Payment Formula

Under the Medicare PFS, payment rates for individual services are based on relative value units (RVUs) for work, practice expense (PE) and malpractice (MP); a dollar conversion factor that is updated annually; and geographic practice cost indices (GPCIs) that account for the geographic variation in the cost of practicing medicine in different areas of the country.

Payment = [(work RVU x work GPCI) + (PE RVU x PE GPCI) + (MP RVU x MP GPCI)] x CF

Note, that as mandated by law, there is a separate fee schedule methodology for anesthesia services. CMS establishes a separate CF for anesthesia services and utilizes the uniform relative guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. A separate methodology for locality adjustments is also necessary.

2016 Medicare Physician Conversion Factor (CF)

√ 2016 Medicare physician conversion factor estimated to be $35.8279

CMS estimates the 2016 Medicare physician conversion factor to be $35.8279, a slight decrease from the 2015 Medicare physician conversion factor of $35.9335. The estimated CY 2016 physician conversion factor reflects a budget neutrality adjustment of -0.02 percent, the 0.5 percent update adjustment factor specified under MACRA, and the -0.77 percent target recapture amount required under The Achieving a Better Life Experience (ABLE) Act of 2014.
ABLE established a 1 percent target for adjustments to misvalued codes for 2016 and required that payments under the fee schedule be reduced by the difference between the target for the year

and the estimated net reduction in expenditures. In CY 2016, the net reduction in expenditures resulting from adjustments to relative values of misvalued codes is 0.23 percent. Since the recapture amount was less than the required 1.0 percent, CMS had to make adjustments elsewhere to capture the remaining 0.77 percent. The agency implemented this mandate through a reduction to the physician conversion factor. This results in an across-the-board reduction to the physician fee schedule.

Table 1: Calculation of the CY 2016 PFS Conversion Factor

Conversion Factor in effect in CY 2015		35.9335
Update Factor	0.50 percent (1.0050)	
CY 2016 RVU Budget Neutrality Adjustment	-0.02 percent (0.9998)	
CY 2016 Target Recapture Amount	-0.77 percent (0.9923)	
CY 2016 Conversion Factor		**35.8279**

The CY 2016 anesthesia conversion factor is estimated to be $22.3309.

MACRA called for an annual update to the conversion factor of 0.5 percent from 2016-2019. With the 2016 physician conversion factor estimated at less than the 2015, it has been reported in the press that organized medicine is very disappointed by the reduced conversion factor for CY 2016 and what is being viewed by some as a broken promise for a raise.

Specialty-Specific Impacts

√ Impact ranges from +9 percent to -4 percent

Table 62 in the final rule, the specialty-specific impact table, provides an estimated impact on total allowed charges by specialty of all finalized proposals for CY 2016. Impacts ranged from -4 percent for gastroenterology to +9 percent for independent laboratories.

The table is a reflection of the impact of policy changes on work, practice expense (PE), and malpractice (MP) RVUs. CMS indicated in the final rule that for CY 2016, the negative changes are driven by two major factors: changes resulting from the Misvalued Code Initiative and technical changes to the MP RVU methodology. The Misvalued Code Initiative was established under the Patient Protection and Affordable care Act (PPACA) and requires CMS to periodically identify and review potentially misvalued codes and make appropriate adjustments in their assigned RVUs.

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

Practice expense RVUs capture the costs of maintaining a practice and are made up of a both a direct cost portion and an indirect costs portion. The direct costs are those that can be assigned to a specific service such as staff time, supplies and equipment. Indirect costs are those that cannot be directly attributed to the provision of a service such as rent or overhead costs.

PE Methodology

√ Technical changes to the PE methodology

Indirect PE per hour data is used in developing the indirect portion of PE RVUs. For CY 2016, CMS incorporated the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014, to develop indirect practice expense per hour data. CMS used a proxy PE per hour (PE/HR) value for interventional cardiology, as there are no Physician Practice Expense Information Survey data for this specialty, by crosswalking the PE/HR for from cardiology, since the specialties furnish similar services in the Medicare claims data. CMS finalized several other refinements to the PE methodology.

CMS also indicated that they have been unable to identify a systematic way of varying the maintenance cost assumption relative to the price or useful life of equipment. CMS noted that it continues to seek a source of publicly available data on actual maintenance costs for medical equipment to improve the accuracy of the equipment costs used in developing PE RVUs.

Changes to Direct PE Inputs for Specific Services

√ Updated PE inputs for specific services

In recent years, CMS has been updating PE inputs for imaging services from film to digital inputs to more accurately reflect current practice. The addition of a Picture Archiving and Communications System (PACS) workstation to the PE database has been part of that change. For CY 2016, CMS finalized a proposal to update the price for the PACS workstation to $5,557 from the current price of $2,501 and update PE inputs to CPT code 76377 (3d render w/intrp postprocess). CMS also finalized a number of other proposals related to the standardization of clinical labor tasks associated with digital imaging and pathology.

In addition, CMS removed the task "complete botox log" from several services, addressed clinical labor inconsistences in several codes, reclassified "freezer" from a direct to indirect PE input, and updated prices for existing direct inputs. CMS noted that it continues to seek stakeholder input regarding the best sources of information for the typical number of blocks and batch sizes for pathology services.

√ Deferral of decision on developing non-facility PE RVUs for cataract surgery

Cataract surgery generally has been performed in an ambulatory surgery center or a hospital outpatient department. CMS has not assigned non-facility (office) PE RVUs under the PFS for cataract surgery, although according to Medicare claims data, there are a relatively small number of these services furnished in non-facility settings. CMS noted in the CY 2016 proposed PFS that it believes that it now may be possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. CMS solicited comments on office-based surgical suite cataract surgery and the direct PE inputs involved in furnishing cataract surgery in the non-facility setting.

Commenters provided information about clinical considerations related to furnishing these services in a non-facility setting, with many commenters citing safety concerns involved in furnishing cataract surgery in the office setting. In the final rule, CMS stated that it will use this

information as it considers whether to proceed with development of non-facility PE RVUs for cataract surgery.

√ Deferral of decision on developing non-facility PE RVUs for functional endoscopic sinus surgery

In the CY 2016 proposed PFS, CMS requested stakeholder input on the appropriate direct PE inputs when endoscopic sinus surgery (CPT codes 31254, 31255, 31256, 31267, 31276, 31287 and 31288) is performed in a non-facility setting. This request is based on stakeholder feedback that changes in technique and technology now allow for these procedures to be performed in a non-facility setting.

In response, the American Medical Association (AMA)/Specialty Society Relative (Value) Update Committee (RUC) indicated an intention to review direct PE inputs at its January 2016 meeting. Another commenter noted that endoscopic sinus surgery services have been identified by a joint workgroup of the CPT Editorial Panel and the RUC for development of bundled codes for this code family. The commenter concluded that inputs will likely be reviewed as part of this process. Other commenters noted clinical concerns about performing this service in the non-facility setting. CMS stated in the final rule that it will use this information as it considers whether to proceed with development of non-facility PE RVUs for functional endoscopic sinus surgery.

Malpractice (MP) RVUs

MP RVUs represent payment for professional liability insurance. Typically MP RVUs make up the smallest portion of a code's total RVU value.

Annual update of MP RVUs

√ Modifications to MP RVU update methodology

In the CY 2016 final rule, CMS finalized a number of modifications to the MP RVU update methodology, including annual updates of MP RVUs rather than every five years, utilization of an average of the three most recent years of available data instead of a single year, and continued maintenance of code-specific overrides when needed.

√ Elimination of MP RVU floor for add-on codes

Currently there is a MP RVU floor of 0.01 for all nationally-priced PFS services. For CY 2016, CMS eliminated the MP RVU floor of 0.01 for add-on codes. MP RVUs for add-on codes will be rounded to 0.00 where calculated MP RVUs are less than 0.0005. CMS made this policy change because add-on codes are always reported with a base code, and as a result, in practice the current method creates a 0.02 floor for any service reported with an add-on code.

√ Adjustment of anesthesia MP RVUs

After delaying implementation in CY 2015, CMS will update anesthesia MP RVUs in CY 2016 using a scaling factor. CMS also finalized some other minor modifications to the MP RVU methodology and specialty overrides for CY 2016.

CY 2016 Identification of Potentially Misvalued Services

As mentioned previously, PPACA contains a provision that promotes identification and correction of misvalued physician fee schedule services. CMS identifies these services through a public nomination process as well as a variety of screens that were listed in the legislation. These screens include:

- Codes (and families of codes as appropriate) for which there has been the fastest growth
- Codes (and families of codes as appropriate) that have experienced substantial changes in PE
- Codes for new technologies or services within an appropriate period (such as 3 years) after the relative values are initially established for such codes
- Multiple codes that are frequently billed in conjunction with furnishing a single service
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment
- Codes which have not been subject to review since the implementation of the
- Resource-Based Relative Value Scale (RBRVS) (also known as the Harvard-valued codes).
- Such other codes determined to be appropriate by the Secretary of Health and Human Services (HHS).

√ Nomination of potentially misvalued services

CMS added one code to its potential misvalued services list through the public nomination process.

Therapeutic apheresis: CPT code 36516 (Apheresis selective), which was publically nominated, has been added to the list of potentially misvalued services. The nominator stated that CPT code 36516 is misvalued because of incorrect direct and indirect PE inputs and an incorrect work RVU.

CMS declined to add publically nominated CPT codes 52441 (Cystourethro w/implant) and 52442 (Cystourethro w/addl implant) to its list of potentially misvalued services.

√ Implanted neurostimulator code family identified as potentially misvalued

CMS is adding the Electronic Analysis of Implanted Neurostimulator family of codes (CPT codes 95970–95982) to the list of potentially misvalued services. In the CY 2015 final PFS, CMS reviewed the based codes (CPT codes 95971–95973) in this family. Because of significant time changes in these codes, CMS believes the entire code family is potentially misvalued.

√ 103 codes added to the potentially misvalued services list under the high expenditure screen

CMS added 103 of the 108 CPT codes originally identified under the high expenditure screen to the potentially misvalued services list. This screen focuses on services with Medicare allowed charges of $10 million or greater. The complete list can be found in Table 8 of the final rule.

√ Anesthesia furnished in conjunction with lower gastrointestinal (GI) procedures

The CPT manual includes more than 400 diagnostic and therapeutic procedures, listed in Appendix G, for which the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the procedure. In developing work and PE RVUs for these services, CMS included the resource costs associated with moderate sedation in the valuation.

CPT codes 00740 (Anesthesia for procedure on GI 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. CMS noted that a separate anesthesia service is now reported more than 50 percent of the time when several types of colonoscopy procedures are reported. Because of the change in frequency of anesthesia and colonoscopy services being reported together, CPT codes 00740 and 00810 have been added to the list of potentially misvalued services. In its comments, the RUC stated that it anticipates reviewing CPT codes 00740 and 00810 as potentially misvalued codes.

CMS also solicited comments in the proposed rule on establishing a uniform approach to valuation for all Appendix G services. CMS will consider these comments and associated recommendations in future rulemaking.

Improving the Valuation and Coding of the Global Package

√ Approach to gathering data on global surgical package to be addressed in future rulemaking

In the recent past, CMS has expressed concerns that current efforts to validate RVUs in the PFS do not go far enough to assess whether the valuation of global surgical packages reflect the number and level of post-operative visits that are typically furnished. As a result, in the CY 2015 PFS final rule CMS finalized a policy to transition all 10-day and 90-day global codes to zero-day global periods. CMS stated that they believed that this would increase the accuracy of PFS payment by setting payment rates for individual services based more closely on the typical resources used.

This policy was never implemented because MACRA, enacted into law on April 16, 2015, prohibited CMS from implementing it. Instead MACRA required that beginning no later than January 1, 2017, CMS will collect data on the number and level of visits furnished during the global period and, beginning in 2019, use this data to improve the accuracy of the valuation of surgical services. 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.

In the CY 2016 proposed rule, CMS solicited comments on the kinds of auditable, objective data that they should collect as well as comments on how this information can be collected both efficiently and accurately. CMS received many comments on how to collect auditable, objective information, as well as many comments on valuing the individual components of the global surgical package. CMS will use these comments as they develop a proposal to be included in future rulemaking. Since CMS must begin collecting this data by January 2017, it is anticipated

this proposal will be included in the 2017 proposed PFS rule scheduled to be released on or around July 1, 2016.

Elimination of the Refinement Panel

√ Refinement panel will not be eliminated

The Refinement Panel process has been used by the agency to consider comments on interim relative values which until CY 2016 were generally published in the final rule. Because of the recent changes in the timing of the valuation of services (proposed values included in the proposed rule (July) instead of interim values included in the final rule (December)), proposed values for most codes that are being valued for CY 2016 were published in the CY 2016 PFS proposed rule. CMS only published interim values in the CY 2016 final rule for a small number of codes where they did not receive recommendations in time to include them in the proposed rule.

Because of this change in the timing of when proposed values are released for public comment, CMS proposed to permanently eliminate the refinement panel beginning in CY 2016, and instead, publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. The majority of commenters opposed the elimination of the refinement panel and CMS is not finalizing this proposal. CMS will retain the ability to convene refinement panels for codes with interim final values when the agency determines it is necessary.

CMS noted to commenters that although they did not finalize the proposal to eliminate the refinement panel, CY 2016 is the final year for which CMS anticipates establishing interim final values for existing services. Thus, it is unlikely there will be many opportunities for CMS to convene this panel in the future.

Improving Payment Accuracy for Primary Care and Care Management Services

The proposed rule had three proposals related to improving payment for primary care services: improving payment for the professional work of care management services, establishing separate payment for collaborative care, and improving beneficiary access to transitional care management (TCM) and chronic care management (CCM) services.

√ CMS to consider comments on add-on codes for cognitive services in future rulemaking

In the proposed rule, CMS solicited comments on developing add-on codes that capture the additional physician work performed by primary care and cognitive specialties when providing for the chronic care needs for particular subsets of Medicare beneficiaries that goes beyond what is already included in E/M services. CMS indicated that they received many comments on this proposal and that they will take them into consideration for future rulemaking.

CMS noted that the AMA and others urged CMS to make separate Medicare payment for existing CPT codes that currently are not separately paid under the PFS, but that describe similar services and for which there are RUC-recommended values. These codes describe a broad range of services, some of which involve non-face-to-face care management over a period of time.

√ CMS to consider comments on payment for collaborative care in future rulemaking
In the proposed rule, CMS sought comments on developing separate payment for two types of collaborative care: general collaborative care and collaborative care for beneficiaries with common behavioral conditions. CMS was interested in the parameters of and resources involved in these collaborations. CMS indicated that it received many positive comments on this proposal and that it will take comments into consideration for future rulemaking.

√ Changes to improve beneficiary access to TCM and CCM services finalized
In CY 2013 CMS established separate payment for TCM services, and in CY 2015 CMS established separate payment for CCM services. CMS recognizes that the reporting requirements for these services exceed those of E/M and other services. In response to feedback from practitioners that the requirements are too burdensome and could interfere with their ability to provide these services, CMS solicited comments on how it could improve beneficiary access to these services.

Based on input from commenters, CMS will develop subregulatory guidance clarifying the intersection of fax transmission and Certified EHR Technology (CEHRT) for the purpose of CCM billing. Regarding TCM services, CMS is adopting recommendations that the required date of service reported on the claim be the date of the face-to-face visit, and to allow (but not require) submission of the claim when the face-to-face visit is completed. CMS will revise existing subregulatory guidance to implement these changes.

CMS also received several comments regarding billing requirements, scope of service elements (such as eliminating the requirement to use CEHRT), clarifying rules regarding fax transmission from certified EHRs, and reporting rules for TCM services (requiring date of service and when claims can be submitted). CMS also received comments that the current payment amounts were not adequate. CMS will take comments into consideration in the development of potential proposals for future rulemaking.

Target for Relative Value Adjustments for Misvalued Services
CMS finalized a number of methodological issues related to calculating the target for relative value adjustments for misvalued services. Background information on the target and the CY 2016 target rate can be found in the Medicare physician conversion factor section of this article.

√ Methodological issues to calculate target determined

- *Distinguishing "Misvalued Code" Adjustment from Other RVU Adjustments*: CMS must identify a subset of the adjustments in RVUs for a year that will be used to calculate the estimated "net reduction" in expenditures. For CY 2016, CMS included the estimated pool of all services with revised input values including any codes for which changes in coding or policies might result in differences in how a given service is reported from one year to the next. CMS excluded CY 2015 interim final value code-level input changes.

- *Calculating "Net Reduction:"* CMS defined the formula it used to calculate the "net reduction." CMS used the net increases and decreases in values for services, including

those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes. Based on input received through the comment process, CMS excluded from the calculation of the "net reduction" in expenditures changes in coding and valuation for services 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. The Advanced Care Planning (ACP) codes are an example of such a service.

- *Measuring Adjustments*: CMS estimated the net reduction in expenditures due to adjustments to RVUs for misvalued codes by comparing the total RVUs of the relevant set of codes (by volume) in the current year to the update year, and dividing that by the total RVUs for all codes (by volume) for the current year. Commenters were generally supportive of this approach.

Phase-In of Significant RVU Reductions

√ Reductions greater than 20 percent phased-in over two years and capped at 19 percent in year 1

Section 220(e) of the Protecting Access to Medicare Act (PAMA) of 2014 specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in RVUs shall be phased-in over a two-year period. CMS finalized a policy that for those codes with a decrease of 20 percent or more, the reduction in 2016 would be capped at 19 percent, with the remaining portion applied in the following year.

Changes for Computed Tomography (CT) Under PAMA

√ CT modifier established to comply with PAMA mandate

On or after January 1, 2016, by legislative mandate, the technical payment for PFS and outpatient prospective payment system (OPPS) services will be reduced for applicable CT services identified by certain CPT/Health Care Common Procedure Coding System (HCPCS) codes furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management." The payment reduction is 5 percent in CY 2016 and increases to 15 percent in subsequent years.

Beginning January 1, 2016, hospitals and suppliers will be required to report the "CT" modifier on claims for CT scans described by any of the HCPCS codes identified as applicable (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scanners.

The applicable CT services are identified by HCPCS codes: 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263 and 75571–75574 (and any succeeding codes).

CY 2016 Valuation of Specific Codes

Process for Valuing New, Revised and Potentially Misvalued Codes

√ New process for valuing codes applicable to all codes in 2017

CY 2016 was the transition year for the new timeline and process for establishing values for services in the PFS. Under the new process, CMS included proposed values for these services in the proposed rule (July), rather than establishing them as interim final in the final rule with comment period (November). For CY 2016, CMS proposed new values in the CY 2016 proposed rule for the codes for which it received complete recommendations from the RUC by February 10, 2015. For recommendations regarding any new or revised codes received after the February 10, 2015, deadline, including updated recommendations for codes included in the CY 2016 proposed rule, CMS established interim final values in this final rule with comment period, consistent with previous practice. Beginning with valuations for CY 2017, the new process will be applicable to all codes.

√ Table 11 lists final CY 2016 work RVUs for new, revised and potentially misvalued services

In this final rule, CMS summarized the process it used to review recommendations from the RUC, the methodology for refining work recommendations from the RUC, and the methodology for establishing direct PE inputs and establishing MP RVUS. Relevant tables from the final rule with key information include the following:

- Table 9: 2016 Final Rule HCPCS Placeholder to CPT Code Numbers
- Table 10: CY 2016 Malpractice Crosswalk
- Table 11: Final CY 2016 work RVUs for New, Revised and Potentially Misvalued Services

CMS indicated that it received invoices for several new supply and equipment items. CMS accepted the majority of these items and added them to the direct PE input database. Tables 18 and 19 detail the invoices received for new and existing items in the direct PE database. CMS addressed comments received on several possible errors in the direct PE database that did not apply to CPT codes under review.

CY 2016 Valuation of Specific Codes

Lower GI Endoscopy Services

√ Updated payment rates for GI services

In CY 2015, CPT revised the lower GI code set, and the RUC provided CMS recommendations for valuing these services. In the CY 2015 final rule, CMS delayed valuing the lower GI codes and proposed values for these codes in the 2016 proposed rule. A summary of the finalized recommendations follow.

- *GI Endoscopy (CPT Codes 43775, 44380–46607 and HCPCS Codes G0104, G0105 and G0121)*: CMS finalized the RUC-recommended value of 3.36 work RVUs for the base colonoscopy code, CPT code 45378, which is slightly higher than the value in the proposed rule, which was 3.28 work RVUs. CMS then adjusted the valuation of all the other codes in the lower GI code set using CPT code 45378 as the base and then applying a methodology known as the incremental difference methodology to calculate the work

RVU values for the other codes in the family. Table 12 summarizes the application of this methodology on the other GI services.

- *Laparoscopic Sleeve Gastrectomy (CPT Code 43775)*: CMS finalized a work RVU of 20.38 for CPT code 43775. CMS established this value by crosswalking the work RVUs for this code from CPT code 37217 (Stent placemt retro carotid).
- *Incomplete Colonoscopy (CPT codes 44388, 45378, G0105 and G0121)*: In 2015, CPT changed the definition of an incomplete colonoscopy. According to Medicare instructions, an incomplete colonoscopy was paid at the same rate as a sigmoidoscopy. CMS is concerned that this may no longer be appropriate under the new definition of an incomplete colonoscopy. CMS sought comments on this issue in the proposed rule. CMS indicated in the final rule these comments will be helpful as it determines if changes need to be implemented.

Radiation Treatment and Related Image Guidance Services

√ Implementation of new radiation treatment code set delayed again

√ Utilization rate assumption for linear accelerators increased

For CY 2015, the CPT Editorial Panel revised the set of codes that describe radiation treatment delivery services based in part on the CMS identification of these services as potentially misvalued in CY 2012. In CY 2015, CMS delayed implementing the new code set and created G-codes that mimic the predecessor CPT codes.

CMS finalized several changes for CY 2016 related to radiation treatment delivery services:

- CMS will not implement the new code set but will instead continue to use the current G-codes and values for 2016.
- CMS will use a 60 percent utilization rate assumption (up from 50 percent) for the linear accelerator for CY 2016. The rate will increase to 70 percent in CY 2017. This increased utilization rate will will have a negative impact on the calculation of PE RVUs for the radiation treatment delivery codes where a linear accelerator is assigned as a direct PE input.
- CMS discussed several issues related to physician time, direct PE inputs and equipment price for one of the new image guidance codes, CPT code 77387 (Guidance for radiat tx dlvr).

CMS stated in the final rule that it will engage in market research to develop independent estimates of utilization and pricing for linear accelerators and image guidance used in furnishing radiation treatment services. CMS will also consider ways in which data collected from hospitals paid under the hospital OPPS may be helpful in establishing rates for these and other technical component services. CMS will consider this information, including public comment, as it develops proposals for inclusion in future notice and comment rulemaking.

Superficial Radiation Treatment Delivery

In the proposed rule, CMS requested recommendations from the RUC and other stakeholders regarding whether physician work should be added and minutes for the radiation therapists should be removed for CPT code 77401 (Superficial radiat tx dlvr). CMS noted that commenters

did not agree on the work involved in CPT code 77401 and that CMS is now considering whether it should create a code to describe the total work associated with the course of treatment for these services. CMS is seeking additional information on alternative descriptions and values for a code describing this work for consideration in future rulemaking.

ACP Services

√ Payment established for ACP services

In CY 2015, the CPT Editorial Panel created two new codes describing ACP services (CPT codes 99497 and 99498). CMS assigned these codes an interim final status indicator of "I" (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services). For CY 2016, CMS is establishing payment for ACP services and changed their status indicator to "A" (Active).

Table 2: Advanced Care Planning Services

HCPCS Code	Long Descriptor	Final CY 2016 Work RVU
99497	Advanced care plan 30 min	1.50
99498	Advanced care plan add'l 30 min	1.40

Currently there is no national Medicare coverage policy for ACP services. In the absence of a national policy, local contractors would remain responsible for local coverage decisions. Many proposed rule commenters suggested that CMS establish a national coverage policy for these services. CMS responded that it would be advantageous to allow time for implementation and experience with ACP services, including identification of any variation in utilization, prior to considering a national coverage policy.

CMS indicated that it is adopting CPT coding guidance for these services. In this case, CPT instructs that CPT codes 99497 and 99498 may be billed on the same day or a different day as other E/M services, and during the same service period as TCM or CCM services and within global surgical periods. CMS is also adopting the CPT guidance prohibiting the reporting of CPT codes 99497 and 99498 on the same date of service as certain critical care services, including neonatal and pediatric critical care.

Valuation of Other Codes for CY 2016

CMS discussed its refinements to recommendations on final work RVUs for codes with proposed work RVUs in the CY 2016 proposed rule. For these codes, CMS either did not accept the RUC-recommended values or there were no RUC recommendations.

Direct PE Input-Only Recommendations

CMS discussed its refinements to recommendations on a set of codes for which it received direct PE recommendations but no work recommendations. CMS also identified these codes as potentially misvalued because their direct PE inputs were not reviewed alongside their work RVUs and time.

CY 2015 Interim Final Codes
CMS discussed its final actions for CY 2016 for codes with CY 2015 interim final work RVUs. Table 13 in the final rule provides a summary of these codes and final actions taken by CMS.

CY 2016 Interim Final Codes
CMS discussed its interim final values for any new or revised codes where recommendations were received after the February 10, 2015, deadline, including updated recommendations for codes included in the CY 2016 proposed rule. CMS established interim final values in this final rule with comment period, consistent with previous practice. Table 15 in the final rule provides a summary of these codes with interim final work RVUs. CMS also included several tables related to PE RVUs and invoices submitted to CMS for various equipment and supplies.

Medicare Telehealth Services
CMS maintains a list of Medicare telehealth services. When services on the list meet conditions specified by CMS (related to location, technology, authorized provider, eligible telehealth individual, *etc.*), Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service.

√ Services added to list of Medicare telehealth services
CMS is adding 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 (CPT codes 90963-90966). CMS declined requests to add several other codes to the list of Medicare telehealth services.

√ CRNAs added to list of distant site practitioners
For CY 2016, CMS finalized a proposal to add CRNAs to the list of distant site practitioners.

Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements
"Incident to" is defined as services or supplies that are furnished incident to a physician's professional services when the services or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness and services are performed in the physician's office or in the patient's home.

√ Two policies related to "incident to" services finalized
In some cases, the physician or practitioner supervising the service is not the same individual treating the patient more broadly. For 2016, CMS finalized a proposal to specify that in those cases, only the supervising physician or practitioner may bill Medicare for "incident to" services.

Additionally, CMS finalized a proposal to require that auxiliary personnel providing "incident to" services and supplies cannot have been excluded from Medicare, Medicaid or other federal health care programs by the Office of Inspector General, or have had their enrollment revoked for any reason at the time that they provide such services or supplies.

Portable X-Ray: Billing of the Transportation Fee

√ Subregulatory guidance language updated to clarify proration policy

CMS finalized a proposed change to the subregulatory guidance in the Medicare Claims Processing Manual (Pub. 100-4, Chapter13, Section 90.3) to clarify the portable X-ray transportation fee proration policy, effective January 1, 2016. CMS believes the revision to the Manual provides consistent direction to all Medicare Administrative Contractors (MACs) in the payment of portable X-ray transportation for Medicare Part B claims and strengthens program integrity.

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

√ Regulatory language related to waiver of deductible for anesthesia services corrected

In the CY 2015 final PFS, CMS stated that the statutory waiver of deductible applies to anesthesia services furnished in conjunction with a colorectal cancer screening test even when a polyp or other tissue is removed during a colonoscopy. CMS inadvertently failed to make this change to regulations. CMS finalized a proposal to correct this error in the CY 2016 final rule.

Therapy Caps

√ CY 2016 therapy cap set at $1,960, and MACRA permits targeted medical reviews

The CY 2016 outpatient therapy cap is $1,960. CMS noted that under section 1833(g)(5) of the Social Security Act (the Act) as amended by section 202(b) of the MACRA, claims exceeding the therapy thresholds are no longer automatically subjected to a manual review process; CMS is permitted to do a more targeted medical review on claims. The statutorily required manual medical review process expires on December 31, 2017.

CCM Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

√ Payment established for CCM services in RHCs and FQHCs

CMS finalized a proposal to establish payment for CCM services beginning on January 1, 2016, for RHCs and FQHCs. CMS proposed to waive the RHC and FQHC face-to-face requirement when furnishing CCM services. Otherwise, the requirements CMS proposed for RHCs and FQHCs to receive payment for CCM services were consistent with the requirements for those providers billing under the PFS. CMS noted that most of the comments it received were very supportive of the proposal to establish payment for CCM services in RHCs and FQHCs.

HCPCS Coding for RHCs

√ RHCs begin reporting HCPCS codes starting April 1, 2016

RHCs are paid an all-inclusive rate (AIR) per visit for medically necessary primary health services and qualified preventive health services furnished face-to-face by an RHC practitioner to a Medicare beneficiary. Currently RHCs must report HCPCS/CPT codes only for preventive services and generally must report revenue codes for everything else. Although HCPCS coding is currently required for approved preventive services on RHC claims, HCPCS coding is not used to determine RHC payment.

CMS finalized a proposal that all RHCs must report every service furnished during an encounter using HCPCS/CPT codes starting April 1, 2016. CMS delayed implementation until April to allow MACs additional time to implement the necessary claims processing systems. Providers would still be required to report a revenue code. CMS clarified that RHCs would continue to be paid under the AIR and there would be no change in their payment methodology.

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

√ Grandfathered tribal FQHCs to be paid based on Indian Health Service (IHS) payment rate

CMS finalized a proposal that tribal facilities grandfathered in as Medicare provider-based entities on or before April 7, 2000, and that have a change of status from IHS-operated to tribally operated and no longer meet Medicare hospital conditions of participation, may seek to become certified as grandfathered tribal FQHCs. CMS also finalized a proposal that these grandfathered tribal FQHCs would be paid based on the IHS payment rates and not the FQHC PPS payment rates. CMS noted that there was significant opposition to this proposal.

Part B Drugs – Biosimilars

√ Biosimilars with same reference product grouped together and paid at same average sales price (ASP)

Section 3139 of the Affordable Care Act (ACA) amended section 1847A of the Act to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar biological products using the ASP methodology. In this final rule, CMS provided a clarification of the Part B biosimilar payment policy. CMS finalized the following proposals:

- Products that rely on a common reference product's biologics license application will be grouped into the same payment calculation for determining the single ASP payment limit.
- As subsequent biosimilar biological products are approved, CMS will receive manufacturers' ASP sales data through the ASP data submission process and publish national payment amounts.
- If no manufacturer data is collected, local contractors will determine prices using any available pricing information, including provider invoices.

CMS clarified that wholesale-acquisition-cost-based payment amount may be used in cases where the ASP during the first quarter of sales is not sufficiently available from the manufacturer to compute an ASP-based payment amount.

CMS stated that it believes that this finalized policy is generally consistent with CMS's current approach to payment for other drugs and biologicals.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

PAMA directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. In this final rule, CMS focused on the process to establish AUC in the Medicare program.

√ Definitions and other aspects of the process to establish an AUC program finalized

CMS finalized definitions or provided clarifications for a number of terms:

- *Ordering professional*: Physician or practitioner who orders that the imaging service be furnished.
- *Furnishing professional*: The physician or practitioner that actually performs the imaging service and provides the interpretation of the imaging study.
- *Applicable setting*: Physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center and any provider-led outpatient setting determined appropriate by the Secretary.
- *AUC definition (additional clarification)*: A collection of individual appropriate use criteria. Individual criteria are information presented in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s).
- *Provider-led entity (PLE)*: National professional medical specialty society or other organization that is composed primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. CMS notes that this would include national professional medical specialty societies (for example, the American College of Radiology and the American Academy of Family Physicians).

CMS noted that applicable AUC become specified when they are developed, modified or endorsed by a qualified PLE.

CMS finalized its proposal that PLEs must submit an application to CMS to become qualified. Applications will be accepted by CMS each year but must be received by January 1. The first deadline is January 1, 2016. PLEs that become qualified for the first five-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021.

CMS indicated in the final rule that it will identify priority clinical areas through annual rulemaking and in consultation with stakeholders beginning in 2017. CMS may also utilize the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to assist in identifying priority clinical areas. Clinical priority areas will be used by CMS to help identify outlier ordering professionals.

CMS stated in the final rule that it remains concerned that non-evidence-based criteria may be developed or endorsed by qualified PLEs. CMS finalized a proposal to establish a public comment process to identify AUC that potentially are not evidence-based through annual PFS rulemaking. CMS anticipates that this will be a standing request in all future rules. CMS will also use the MEDCAC to further review the AUC, as needed. Additionally, CMS added regulatory language that would allow it to take steps to remove non-evidence-based AUC and language to help facilitate the public comment process.

Physician Performance Initiatives

Physician Compare Website

Mandated by the ACA, Physician Compare is a website created and maintained by CMS that allows beneficiaries to search for physicians and other health care professionals who provide Medicare services. In addition to general practice data, the website includes a variety of quality and patient experience data.

Currently, website users can view information about approved Medicare professionals, such as name, primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare assignment status, education, residency and American Board of Medical Specialties board certification information. For group practices, users also can view group practice names, specialties, practice locations, Medicare assignment status and affiliated professionals. Table 25 in the final rule provides a summary of previously finalized policies for public reporting on Physician Compare.

The 2016 PFS final rule continues the phased approach to public reporting on Physician Compare. CMS will continue to make all 2016 individual eligible professional (EP) and group practice PQRS measures available for public reporting. All Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS measures for groups of two or more eligible providers (EPs) who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor are available for public reporting. In addition, all Accountable Care Organization (ACO) measures, including CAHPS for ACOs, are available for public reporting.

√ Numerous additions to the Physician Compare website finalized

CMS finalized a number of proposals related to enhancing the information available on Physician Compare:

- Practice information to be added
  - Certifying board, and specifically add American Board of Optometry Board Certification and American Osteopathic Association Board Certification
- New measure information to be added
  - Indicator on profile pages for individual EPs who satisfactorily report the new PQRS Cardiovascular Prevention measures group in support of the Million Hearts initiative
  - Group-level QCDR measures
  - Item- (or measure-) level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology
- Medicare program information to be added
  - Include in the downloadable database 1) the Value Modifier tiers for cost and quality, noting if the group practice or EP is high, low or neutral on cost and quality; 2) a notation of the payment adjustment received based on the cost and

quality tiers; and 3) an indication if the individual EP or group practice was eligible to but did not report quality measures to CMS
    - Report in the downloadable database utilization data for individual providers

CMS did not finalize the proposal to include a visual indicator on profile pages for group practices and individual EPs that receive an upward adjustment for the Value Modifier. Table 26 in the final rule provides a summary of participation and measure data newly finalized for public reporting.

Consistent with existing policies, all posted data must meet public reporting standards: measures must be statistically accurate, valid, reliable and comparable, and must resonate with consumers. For individual and group-level measures, CMS will publicly report all measures submitted, reviewed, and deemed valid and reliable in the Physician Compare downloadable file. However, not all measures will be included on the Physician Compare profile pages.

Physician Payment, Efficiency and Quality Improvements – PQRS
In this section of the rule, CMS addresses proposals related to the 2018 PQRS payment adjustment, which will be based on EP or group practice reporting of quality measures during CY 2016.

√ Details finalized for 2018 PQRS payment adjustment
CMS finalized a number of proposals:

- Satisfactorily reporting criteria
    - The criteria for satisfactorily reporting in the 2018 PQRS program (CY 2016 reporting year) is unchanged from the 2017 PQRS program (CY 2015 reporting year)
- Measure changes
    - Tables 29–33 in the final rule summarize various measure changes
    - CMS finalized its proposal to add three new measure groups: Cardiovascular Prevention Measures Group, Diabetic Retinopathy Measures Group and Multiple Chronic Conditions Measures Group
    - CMS finalized a proposal to make modifications to four measure groups: Dementia Measures Group, Diabetes Measures Group, Preventive Care Measures Group and Rheumatoid Arthritis Measures Group
- Auditing of vendors that submit quality measures
    - CMS indicated in the final rule that it is in the process of auditing PQRS participants, including vendors that submit quality measures data
    - CMS finalized a proposal that beginning in 2016, any vendor submitting quality measures for the PQRS must make available to CMS the contact information (at a minimum the phone number, address and e-mail) of each provider on behalf of whom it submits data, and must retain all data submitted to CMS for the PQRS program for a minimum of seven years
- QCDR reporting mechanism

- CMS finalized a number of modifications to the requirements to become a QCDR and a qualified registry

MACRA consolidates the current physician performance programs (PQRS, EHR Incentive Program and the Value Based Payment Modifier) into a single Merit Based Incentive Payment System (MIPS). MACRA also allows providers participating in Alternative Payment Models (APMs) to opt out of MIPS. The first year of the MIPS program is 2019, but physicians will begin reporting in 2017 since there is a two-year lag between reporting measures and the application of an adjustment.

In the proposed rule, CMS solicited comments on quality measures for the MIPS program and on activities that could be classified as clinical improvement activities under the MIPS program. CMS indicated that it received numerous comments on the MIPS program and that these comments will help inform future rulemaking. CMS also noted that on October 1, 2015, it released a Request for Information (80 FR 59102-59113) asking for additional public comment on more detailed questions related to both MIPS and APMs.

Electronic Clinical Quality Measures and Certification Criteria and EHR Incentive Program – Comprehensive Primary Care (CPC) Initiative and Medicare Meaningful Use Aligned Reporting
Providers must report the most recent version of the electronic specifications for clinical quality measures (CQMs) if they choose to report CQMs electronically for the Medicare EHR Incentive Program. In this section of the final rule, CMS finalized proposals related to this issue and alignment with the CPC Initiative.

√ Proposal to enhance program alignment finalized
CMS finalized a proposal that providers participating in PQRS and the EHR Incentive Programs under the 2015 Edition possess EHRs that have been certified to report CQMs according to the format that CMS requires for submission.

Under the CPC Initiative, beginning in 2014, CPC practice sites are required to report to CMS a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for providers to report under the EHR Incentive Program. CMS finalized its proposal to align EHR reporting under the CPC Initiative. In this final rule, CMS finalized a proposal that providers who are part of a CPC practice site and are in their first year of demonstrating meaningful use (in CY 2016) may report CQMs through the CPC group reporting option for CY 2016, and if submitted successfully in accordance with the requirements established by the CPC Initiative and using CEHRT, their CPC reporting would satisfy the CQM requirement for the Medicare EHR Incentive Program. First-year EPs who successfully report CQMs through the CPC group reporting option for the CY 2016 reporting period and meet all other requirements for the Medicare EHR Incentive Program would avoid the meaningful use payment adjustment under Medicare in CY 2018.

Discussion and Acknowledgement of Public Comments Received on the Potential Expansion of the CPC Initiative
The CPC Initiative is a multi-payer, patient-centered medical home initiative that is scheduled to end on December 31, 2016. CMS proposed to expand the CPC Initiative. In the proposed rule, CMS solicited comments on this proposal.

√ Comments acknowledged, but decision on expansion yet to be determined
CMS received 90 comments on the proposal to expand the CPC Initiative. These comments, submitted by a variety of stakeholders, broadly supported the expansion of the program. The decision of whether or not to expand will be made by the Secretary of Health and Human Services in coordination with CMS and the Office of the Chief Actuary and it will be based on whether findings about the initiative meet the statutory criteria for expansion. Given that further evaluation is needed to determine the initiative's impact on both Medicare cost and quality of care, CMS did not finalize the proposal in this final rule.

CMS acknowledged the comments received on this proposal and stated that if the program is expanded in the future, these comments will be considered in the development of proposals included in future rulemaking.

Medicare Shared Savings Program
The Medicare Shared Savings Program was established by the ACA. Eligible groups of providers and suppliers, including physicians, hospitals and other health care providers, may participate in the Shared Savings Program by forming or participating in an ACO.

√ Shared Savings Program changes focus on measures and PQRS
In the 2016 final rule, CMS finalized several policies:

- Quality measures: CMS will add a measure of 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; CMS will preserve the 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
- Satisfying PQRS requirements: CMS clarified how PQRS-EPs participating within an ACO meet their PQRS reporting requirements when their ACO satisfactorily reports quality measures
- Skilled Nursing Facility claims: CMS amended 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
The value-based payment modifier applies to specific physicians and groups of physicians that the Secretary determined were appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. It provides for differential payment to a physician or group of physicians under the PFS based upon the quality of care furnished compared to the cost

of care during a performance period by providing an adjustment made on a per-claim basis. It is applied at the Taxpayer Identification Number (TIN) level.

√ CY 2018 adjustment set, implementation of Value Modifier on nonphysician providers addressed

CMS implemented numerous policies related to the CY 2018 Value Modifier adjustment. Highlights of some of the most significant finalized proposals are described below. A more detailed list of changes implemented in the CY 2016 final rule can be found in the CMS fact sheet on the final rule.

- Nonphysician EPs: The Value Modifier will apply to Medicare PFS payments made to non-physician EPs for the first time
- Quality Tiering: CMS will apply the quality-tiering methodology to all groups and solo practitioners that meet the criteria to avoid the downward adjustment under the PQRS but group practices comprised solely of nonphysicians and nonphysicians who are solo practitioners will be held harmless from downward adjustments
- Upward Adjustment: CMS will continue to set the maximum upward adjustment under the quality-tiering methodology for the CY 2018 Value Modifier at +4.0 times an adjustment factor (to be determined after the conclusion of the performance period) for groups of physicians with 10 or more EPs; +2.0 times an adjustment factor for groups of physicians with between two to nine EPs and physician solo practitioners; and +2.0 times an adjustment factor for groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs and CRNAs
- Payment Risk: CMS will set the amount of payment at risk under the CY 2018 Value Modifier to -4.0 percent for groups of physicians with 10 or more EPs; -2.0 percent for groups of physicians with between two to nine EPs and physician solo practitioners; and -2.0 percent for groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs and CRNAs.

In this section of the final rule, CMS also provided an update on its recent activities related to the Physician Feedback Program. The Physician Feedback Program provides comparative performance information to physicians and medical practice groups as part of Medicare's efforts to improve the quality and efficiency of medical care furnished to Medicare beneficiaries. CMS noted that it intends to release the 2014 Quality Resource Use Report (QRUR) Experience Report in early 2016. This report will provide a detailed analysis of the impact of the 2016 Value Modifier policies on groups of 10 or more providers subject to the Value Modifier in CY 2016, including findings based on the data contained in the 2014 QRURs for all groups and solo practitioners.

Physician Self-Referral Updates

√ Physician self-referral updated to accommodate payment reform, reduce administrative burden and facilitate compliance

The Stark Law addresses physician self-referral issues and prohibits physicians from making referrals for services covered by government programs to entities in which they have financial interests unless they meet certain exceptions. CMS indicated in the rule that CMS is

implementing these changes to facilitate health care delivery and payment systems reform and reduce burden. Highlights of some of the most significant finalized proposals are described below.

- Exceptions: The final rule established two new exceptions. The first exception permits payment by hospitals, FQHCs and RHCs to physicians for the purpose of compensating nonphysician practitioners under certain conditions. The second 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.
- Updating physician-owned hospital requirements: The ACA established new restrictions on physician-owned hospitals. The physician ownership calculation change takes effect on January 1, 2017. CMS updated the regulations related to website and advertising requirements. CMS also finalized changes that better align the regulations to the statute as it related to calculating a hospital's physician ownership percentage.
- Reducing burden through clarifying terminology and providing policy guidance: In response to feedback CMS has received through review of self disclosures, CMS is clarifying terminology and providing guidance in a number of areas to help reduce perceived or actual noncompliance. Some of the more significant updates are listed below. Please note, that this is not a complete list of the changes.
    - Clarifying that compensation paid to a physician organization cannot take into account the referrals of any physician in the physician organization, not just a physician who stands in the shoes of the physician organization, and that employees and independent contractors need not sign arrangements between the physician organization and a designated health services (DHS) entity
    - Clarifying that the writing required in many of the exceptions to the physician self-referral law's referral and billing prohibitions can be a collection of documents (as opposed to a single formal contract) and making the terminology that describes types of arrangements consistent throughout the regulations
    - Clarifying that the term of a lease or personal service arrangement need not be in writing if the arrangement lasts at least one year and is otherwise compliant
    - Allowing expired leasing and personal services arrangements to continue indefinitely on the same terms if otherwise compliant

Private Contracting/Opt-Out

√ Opt-out regulatory language revised to address changes implemented by MACRA

Effective January 1, 1998, section 1802(b) of the Act permits certain physicians and practitioners to opt-out of Medicare if certain conditions are met, and to furnish through private contracts services that would otherwise be covered by Medicare.

The private contracting/opt-out provision was recently amended by MACRA. Prior to the MACRA amendments, the law specified that physicians and practitioners may opt-out for a two-year period. Individuals that wished to renew their opt-out at the end of a two-year opt-out period were required to file new affidavits. MACRA amended section 1802(b)(3) of the Act to require

that opt-out affidavits filed on or after June 16, 2015, automatically renew every two years. Therefore, physicians and practitioners who file opt-out affidavits on or after June 16, 2015, will no longer be required to file renewal affidavits to continue their opt-out status. The amendments further provide that physicians and practitioners who have filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a two-year opt-out period may cancel the automatic extension by notifying CMS at least 30 days prior to the start of the next two-year opt-out period.

CMS finalized a proposal to revise the regulations governing the requirements and procedures for private contracts at 42 CFR part 405, subpart D, so that they conform with these statutory changes.

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

√ CY 2016 list of codes posted

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain DHS to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. The entire scope of four DHS categories is defined in a list of CPT/HCPCS codes, which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications.

The updated, comprehensive code list effective January 1, 2016, is available on the CMS website.

Tables 50 and 51 in the final rule identify the additions and deletions, respectively, to the comprehensive code list that become effective January 1, 2016.

For more information, please contact Sheila Madhani or Eric Zimmerman.