The Centers for Medicare and Medicaid Services (CMS) released the review copy of the 2015 Medicare Physician Fee Schedule (MPFS) proposed rule on July 8, 2015. The American College of Radiology (ACR) will be submitting comments to CMS addressing issues of concern by the deadline on September 8th. Following are highlights of the proposed rule.

Conversion Factor and Impacts (page 709)

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 established the update factor for calendar years 2015 through 2025. To calculate the conversion factor for the update year, CMS multiplied the product of the current year conversion factor and the update factor by the budget neutrality adjustment. They estimate the CY 2016 MPFS conversion factor to be $36.1096, which reflects a budget neutrality adjustment of 0.9999 and the 0.5 percent update factor specified under MACRA.

CMS notes that Section 220(d) of the PAMA added a new paragraph to the Act to establish an annual target for reductions in MPFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the MPFS in accordance with the existing budget neutrality requirement. This is discussed in detail below.

Because CY 2016 represents a transition year in the new process of proposing values for new, revised and misvalued codes in the proposed rule, rather than establishing them as interim final in the final rule with comment period, CMS was not able to calculate a realistic estimate of the target amount at the time the proposed rule was published. Therefore, CMS did not incorporate the impact of the target into the calculation of the proposed conversion factor. However, CMS did estimate the net reduction in expenditures as a result of proposed adjustments to the relative value established for misvalued codes in this proposed rule, not including interim final changes that will be established in the CY2016 MPFS final rule. The net reduction is approximately 0.25 percent of the estimated amount of expenditures under the fee schedule for CY 2016.
Below is an excerpt from Table 45 on page 711: CY 2016 MPFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Allowed Charged (mil)</th>
<th>Impact of Work of RVU Changes</th>
<th>Impact of PE RVU Changes</th>
<th>Impact of MP RVU Changes</th>
<th>Combined Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIAGNOSTIC TESTING FACILITY</td>
<td>$719</td>
<td>0%</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>INTERVENTIONAL RADIOLOGY</td>
<td>$296</td>
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<td>1%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>NUCLEAR MEDICINE</td>
<td>$46</td>
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<td>0%</td>
</tr>
<tr>
<td>PORTABLE X-RAY SUPPLIER</td>
<td>$103</td>
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</tr>
<tr>
<td>RADIATION ONCOLOGY</td>
<td>$1,769</td>
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<td>0%</td>
<td>-3%</td>
</tr>
<tr>
<td>RADIATION THERAPY CENTERS</td>
<td>$52</td>
<td>0%</td>
<td>-9%</td>
<td>0%</td>
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</tr>
<tr>
<td>RADIOLOGY</td>
<td>$4,472</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Multiple Procedure Payment Reduction (MPPR)**

In the proposed rule, CMS did not address MPPR or the statutory requirement that they provide the data to support the application of the MPPR to the professional component (PC) of imaging services.

**Practice Expense Inputs for Digital Imaging Services (Page 43)**

CMS is proposing 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. **CMS is seeking comment on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes.**

In addition to the workstation used by the clinical staff acquiring the images and furnishing the technical component of the services, CMS indicated that a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the professional component of many of these services. CMS stated that they generally believe that workstations used by these practitioners are more accurately considered indirect costs associated with the professional component of the service. However, they understand that the professional workstations for interpretation of digital images are similar in principle to some
of the previous film inputs incorporated into the global and technical components of the codes. Given that many of these services are reported globally in the nonfacility setting, CMS believes it may be appropriate to include these costs as direct inputs for the associated HCPCS codes. Based on established methodology, these costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code. CMS is seeking comment on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes.

CMS indicated that a stakeholder expressed concern about the changes in direct PE inputs for Current Procedural Terminology® (CPT) code 76377, (3D radiographic procedure with computerized image post-processing), that were proposed and finalized in CY 2015 rulemaking as part of the film to digital change. Based on a recommendation from the RUC, CMS removed the input called “computer workstation, 3D reconstruction CT-MR” from the direct PE input database and assigned the associated minutes to the proxy for the PACS workstation. CMS is seeking comment from stakeholders about whether or not the PACS workstation used in imaging codes is the same workstation that is used in the postprocessing described by CPT code 76377, or if more specific workstation should be incorporated in the direct PE input database.

**Appropriate Use Criteria for Advanced Diagnostic Imaging Services** (Page 352)

CMS states that the goal of this statutory appropriate use criteria (AUC) program is to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging. CMS also acknowledges the consensus that AUC programs are preferable to across the board payment reductions that do not differentiate interventions that add value from those that cause harm or add no value.

CMS discusses their experiences and lessons learned from the Medicare Imaging Demonstration (MID) which was a 2-year program that began in October 2011. CMS believes that a successful program would allow flexibility, and they foresee competing sets of AUC developed by different provider-led entities, and competing CDS mechanisms from which providers may choose.

CMS states that in the time since the legislation was enacted, they have met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program. They indicate that having this open door with stakeholders has greatly informed their proposed policy.

CMS then goes into the four major components of the AUC program.

*Establishment of AUC by November 15, 2015*

Applicable AUC may be specified only from among AUC developed or endorsed by national professional medical specialty societies or other provider-led entities. The Act identifies certain considerations the Secretary must take into account when specifying applicable AUC including whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and
are based on studies that are published and reviewable by stakeholders. The Act requires the Secretary to review the specified applicable AUC each year to determine whether there is a need to update or revise them, and to make any needed updates or revisions through rulemaking. If the Secretary determines that more than one AUC applies for an applicable imaging service, the Secretary shall apply one or more AUC for the service.

CMS is proposing to define the term, “provider-led entity,” so that the public has an opportunity to comment, and entities meeting the definition are aware of the process by which they may become qualified under Medicare to develop or endorse AUC. Under the proposed process, once a provider-led entity is qualified (which includes rigorous AUC development requirements involving evidence evaluation, as provided in section 1834(q)(2)(B) of the Act and proposed in this proposed rule) the AUC that are developed or endorsed by the entity would be considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act.

Mechanisms for consultation with AUC by April 1, 2016

The second major component of the Medicare AUC program is the identification of qualified CDS mechanisms that could be used by ordering professionals for consultation with applicable AUC under the Act. CMS envisions a CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user. The ordering professional would input information regarding the clinical presentation of the patient into the CDS tool, which may be a feature of or accessible through an existing system, and the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, multiple CDS mechanisms would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology (IT) systems. This would minimize burden on provider teams and avoid duplicate documentation.

All CDS mechanisms must meet the requirements of the Act which specifies that a mechanism must: make available to the ordering professional applicable AUC and the supporting documentation for the applicable imaging service that is ordered; where there is more than one applicable AUC specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDS was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Section 1834(q)(3)(C) of the Act specifies that the Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDS mechanisms.

CMS does not include a proposal to implement CDS mechanism in this rule, but will be discussed further in the 2017 MFS proposed rule. CMS anticipates that the initial list of specified applicable CDS mechanisms will be published sometime after the CY 2017 MPFS final rule. In advance of these actions, CMS will continue to work with stakeholders to understand how to
ensure that appropriate mechanisms are available, particularly with respect to standards for certified health IT, including EHRs, that can enable interoperability of AUC across systems.

**AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017**

This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a listed qualified CDS mechanism when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional’s consultation with a qualified CDS mechanism. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders the imaging service is usually not the same professional who bills Medicare for the test when furnished.

CMS anticipates including further discussion and adopting policies regarding claims-based reporting requirements in the CY 2017 and CY 2018 rulemaking cycles.

**Annual identification of outlier ordering professionals for services furnished after January 1, 2017**

The identification of outlier ordering professionals under this section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Although, CMS is not including proposals to implement these sections in this proposed rule, they are proposing to identify outlier ordering professionals from within priority clinical areas that would be established through subsequent rulemaking. In this rule, they propose a process to provide clarity around priority clinical areas.

**Proposals for Implementation**

1) **Definitions**

The AUC program only applies in applicable settings. An applicable setting would include a physician’s office, a hospital outpatient department (including an emergency department) and an ambulatory surgical center. Further, the proposed program only applies to applicable imaging services. These are advanced diagnostic imaging services for which one or more applicable AUC apply, one or more qualified CDS mechanisms is available, and one of those mechanisms is available free of charge.

**CMS is proposing to add the following language to the definition of AUC:** AUC are a collection of individual appropriate use criteria. Individual criteria are information presented in a manner that links: a specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s).

A provider-led entity would include national professional medical specialty societies (for example the American College of Radiology and the American Academy of Family Physicians)
or an organization that is comprised primarily of providers and is actively engaged in the practice
and delivery of healthcare (for example hospitals and health systems). Applicable
AUC become specified when they are developed, modified or endorsed by a qualified provider-
led entity. A provider-led entity is not considered qualified until CMS makes a determination via
the qualification process discussed in this proposal. CMS is introducing priority clinical areas to
inform ordering professionals and furnishing professionals of the clinical topics, clinical topics
and imaging modalities or imaging modalities that may be identified by the agency through
annual rulemaking and in consultation with stakeholders which may be used in the identification
of outlier ordering professionals.

2) AUC Development by Provider-Led Entities

CMS recognizes that it is not feasible for them to review every individual criterion. Therefore,
they propose to establish a qualification process and requirements for qualified provider-led
entities in order to ensure that the AUC development or endorsement processes used by a
provider-led entity result in high quality, evidence-based AUC in accordance with section
1834(q)(2)(B). Therefore, **CMS proposes that AUC developed, modified, or endorsed by
qualified provider-led entities will constitute the specified applicable AUC that ordering
professionals would be required to consult when ordering applicable imaging services.**

In order to become and remain a qualified provider-led entity, CMS proposes to require a
provider-led entity to demonstrate adherence to specific requirements when developing,
modifying or endorsing AUC. The first proposed requirement is related to the evidentiary review
process for individual criteria. **Entities must engage in a systematic literature review of the
clinical topic and relevant imaging studies.** CMS would expect the literature review to
include evidence on analytical validity, clinical validity, and clinical utility of the specific
imaging study. In addition, the provider-led entity must assess the evidence using a formal,
published, and widely recognized methodology for grading evidence. Consideration of
relevant published evidence-based guidelines and consensus statements by professional
medical specialty societies must be part of the evidence assessment. Published consensus
statements may form part of the evidence base of AUC and would be subject to the
evidentiary grading methodology as any other evidence identified as part of a systematic
review.

In addition, **CMS proposes that the provider-led entity’s AUC development process must be
led by at least one multidisciplinary team with autonomous governance that is accountable
for developing, modifying, or endorsing AUC. At a minimum, the team must be composed
of three members including one with expertise in the clinical topic related to the criterion
and one with expertise in imaging studies related to the criterion.** CMS encourages such
teams to be larger, and include experts in each of the following domains: statistical analysis
(such as biostatistics, epidemiology, and applied mathematics); clinical trial design; medical
informatics; and quality improvement. A given team member may be the team’s expert in more
than one domain. These experts should contribute substantial work to the development of the
criterion, not simply review the team’s work.
CMS also proposes that the provider-led entity must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The provider-led entity must disclose any direct or indirect relationships, as well as ownership or investment interests, among the multidisciplinary team members or immediate family members and organizations that may financially benefit from the AUC that are being considered for development, modification or endorsement.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, CMS proposes that the provider-led entity must maintain on its website each criterion that is part of the AUC that the entity has considered or is considering for development, modification, or endorsement. This public transparency of individual criteria is critical not only to ordering and furnishing professionals, but also to patients and other health care providers who may wish to view all available AUC.

CMS recognizes that not all aspects of a criterion will be evidence-based, and that a criterion does not exist for every clinical scenario. They believe it is important for AUC users to understand which aspects of a criterion are evidence-based and which are consensus based. Therefore, CMS proposes that key decision points in individual criteria be graded in terms of strength of evidence using a formal, published, and widely recognized methodology. This level of detail must be part of each AUC posted to the entity’s website.

Finally, CMS proposes that a provider-led entity’s process for developing, modifying, or endorsing AUC (which would be inclusive of the requirements being proposed in this rule) must be publicly posted on the entity’s website.

Under the proposed AUC program, local adaptation of AUC might happen in three ways. First, compatibility with local practice is something that ordering professionals can assess when selecting AUC for consultation. Second, professional medical societies (many of which have state chapters) and large health systems (which incorporate diverse practice settings, both urban and rural) that become qualified provider-led entities can get local feedback at the outset and build alternative options into the design of their AUC. Third, local provider-led entities can themselves become qualified to develop, modify, or endorse AUC.

3) Process for Provider-Led Entities to Become Qualified to Develop, Endorse, or Modify AUC

CMS is proposing that provider-led entities must apply to CMS to become qualified. They are proposing that entities that believe they meet the definition of provider-led submit applications to us that document adherence to each of the qualification requirements. The application must include a statement as to how the entity meets the definition of a provider-led entity. Applications will be accepted each year but must be received by January 1. A list of all applicants that CMS determines to be qualified provider-led entities will be posted on the CMS website by the following June 30 at which time all AUC developed or endorsed by that provider-led entity will be considered to be specified AUC. All qualified provider-led entities must re-apply every 6 years and their applications must be received by January 1 during the 5th year of their approval.
4) Identifying Priority Clinical Areas

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

To identify these priority clinical areas, CMS may consider incidence and prevalence of diseases, as well as the volume, variability of utilization, and strength of evidence for imaging services. They may also consider applicability of the clinical area to a variety of care settings, and to the Medicare population. CMS is proposing to annually solicit public comment and finalize clinical priority areas through the MPFS rulemaking process beginning in CY 2017. To further assist in developing the list of proposed priority clinical areas, CMS is proposing to convene the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), a CMS FACA compliant committee, as needed to examine the evidence surrounding certain clinical areas. Future rulemaking will address additional details.

5) Identification of Non-Evidence-Based AUC

In order to address the concern that some of the AUC developed by qualified provider-led entities may not be evidence-based, CMS is proposing a process by which they would identify and review potentially non-evidence-based criteria that fall within one of the identified priority clinical areas. CMS is proposing to accept public comment through annual MPFS rulemaking so that the public can assist in identifying AUC that potentially are not evidence-based. CMS foresees this being a standing request for comments in all future rules regarding AUC. CMS is also proposing to use the MEDCAC to further review the evidentiary basis of these identified AUC, as needed. If a number of criteria from an AUC library are identified as being insufficiently evidence-based, and the provider-led entity that produced the library does not make a good faith effort to attempt to correct these in a timely fashion, this information could be considered when the provider-led entity applies for re-qualification.

Summary

CMS believes the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDS mechanism developers. It is for these reasons CMS is proposing a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program.

CMS invites the public to submit comments on these proposals.
Phase-in of Significant RVU Reductions (Page 106)

As a result of lobbying efforts by the ACR, Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, also 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 work, PE, and MP RVUs shall be phased-in over a 2-year period. Although the PAMA required the phase-in to begin for 2017, section 202 of the ABLE Act amended section 1848(c)(7) of the Act to require that the phase-in begin for CY 2016.

CMS is proposing a methodology to implement this statutory provision. In developing this proposed methodology, CMS identified several aspects of their approach for which they are specifically seeking comment, given the challenges inherent in implementing this provision in a manner consistent with the broader statutory construct of the MPFS.

Identifying Services that are Not New or Revised Codes

As described in this proposed rule, the statute specifies that services described by new or revised codes are not subject to the phase-in of RVUs. This exclusion recognizes the reality that there is no practical way to phase-in over 2 years changes to RVUs that occur as a result of a coding change for a particular service because there is no relevant reference code or value on which to base the transition. To determine which services are described by new or revised codes for purposes of the phase-in provision, CMS is proposing to apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and to exclude codes that describe different services in the current and update year. This approach would exclude services described by new codes or existing codes for which the descriptors were altered substantially for the update year to change the services that are reported using the code. CMS would also exclude as new and revised codes those codes that describe a different set of services in the update year when compared to the current year by virtue of changes in other, related codes, or codes that are part of a family with significant coding revisions. For example, significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family would also help to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. This proposed application of the phase-in would also be consistent with previous RVU transitions, especially for PE RVUs, for which CMS only applied transition values to those codes that described the same service in both the current and the update years. CMS would also exclude from the phase-in as new and revised codes those codes with changes to the global period, since the code in the current year would not describe the same units of service as the code in the update year.
Estimating the 20 Percent Threshold

Because the phase-in of RVUs falls within the budget neutrality requirements specified in the Act, CMS is proposing to estimate total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. They recognize that the result of this approach could mean that some codes may not qualify for the phase-in despite a reduction in RVUs that is ultimately slightly greater than 20 percent due to budget neutrality adjustments that are made after identifying the codes that meet the threshold in order to reflect the phase-in values for other codes. CMS believes the only alternative to this approach is not practicable, since it would be circular, resulting in cyclical iteration.

RVUs in the First Year of the Phase-In

The Act states that the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period when the RVU reduction for a code is estimated to be equal to or greater than 20 percent. CMS believes that there are two reasonable ways to determine the portion of the reduction to be phase-in for the first year. Most recent RVU transitions have distributed the values evenly across several years. For example, for a 2-year transition CMS would estimate the fully implemented value and set a rate approximately 50 percent between the value for the current year and the value for the update year. CMS believes that this is the most intuitive approach to the phase-in and is likely the expectation for many stakeholders.

However, CMS believes that the 50 percent phase-in in the first year has a significant drawback. For instance, since the statute establishes a 20 percent threshold as the trigger for phasing in the change in RVUs, under the 50 percent phase-in approach, a service that is estimated to be reduced by a total of 19 percent for an update year would be reduced by a full 19 percent in that update year, while a service that is estimated to be reduced by 20 percent in an update year would only be reduced 10 percent in that update year. The logical alternative approach is to consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach would be to reduce the service by the maximum allowed amount (that is, 19 percent) in the first year, and then phase in the remainder of the reduction in the second year. Under this approach, the code that is reduced by 19 percent in a year and the code that would otherwise have been reduced by 20 percent would both be reduced by 19 percent in the first year, and the latter code would see an additional 1 percent reduction in the second year of the phase-in. For most services, this would likely mean that the majority of the reduction would take place in the first year of the phase-in. However, for services with the most drastic reductions (greater than 40 percent), the majority of the reduction would take place in the second year of the phase-in.

After considering both of these options, CMS is proposing to consider the 19 percent reduction as the maximum 1-year reduction and to phase-in any remaining reduction greater than 19 percent in the second year of the phase-in. They believe that this approach...
is more equitable for codes with significant reductions but that are less than 20 percent. CMS is seeking comment on this proposal.

Applicable Adjustments to RVUs

The phase-in provision instructs that the applicable adjustments in work, PE, and MP RVUs be phased-in over 2 years for any service that would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total RVUs for the previous year. However, for several thousand services, CMS develops separate RVUs for facility and nonfacility sites of service. For nearly one thousand other services, including imaging services, they develop separate RVUs for the professional and technical components of the service and sum those RVUs to allow for global billing. Therefore, for individual practitioners furnishing particular services to Medicare beneficiaries, the relevant changes in RVUs for a particular code are based on the total RVUs for a code for a particular setting (facility/nonfacility) or for a particular component (professional/technical.) CMS believes the most straightforward and fair approach to addressing both the site of service differential and the codes with professional and technical components is to consider the RVUs for the different sites of service and components independently for purposes of identifying when and how the phase-in applies. CMS is proposing, therefore, to estimate whether a particular code meets the 20 percent threshold for change in total RVUs by taking into account the total RVUs that apply to a particular setting or to a particular component. Therefore, if the change in the total RVUs for the technical component of a service meets the 20 percent threshold, then that change would be phased-in over 2 years, even if the change for the professional component did not meet the threshold. (Because the global is the sum of the professional and technical components, the portion of the global attributable to the technical component would then be phased-in, while the portion attributable to the professional component would not be.) Since variation of PE RVUs is the only constant across all individual codes, codes with site of service differentials, and codes with professional and technical components, CMS is proposing to apply all adjustments for the phase-in to the PE RVUs.

Changes for Computed Tomography (CT) under the Protecting Access to Medicare Act of 2014 (PAMA) (Page 112)

Section 218(a)(1) of PAMA mandates that for the technical component of applicable computed tomography services paid under the physician fee schedule and HOPPS that a 5-percent reduction in 2016 and a 15-percent reduction in 2017 and subsequent years be made for services furnished using equipment that does not meet the requirements of the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013, entitled “Standard Attributes on CT Equipment Related to Dose Optimization and Management.” To implement this provision, CMS will create modifier “CT” (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 in 2016, claims for CT scans described by above-listed CPT codes (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scans must include modifier “CT” and that modifier will result in the applicable payment reduction for the service.
For CY 2016, CMS is proposing a technical improvement to the PE RVU methodology. CMS proposes 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. Historically, in allowing the current PE RVUs to determine the size of the base PE pool in the PE methodology, CMS has assumed that the relationship of PE RVUs to work RVUs is constant from year to year. Since this is not ordinarily the case, by not considering the proposed aggregate work RVUs in determining the size of the base PE pool, there has been some minor instability from year to year in the relative shares of work, PE, and MP RVUs. While this proposed modification would result in greater stability in the relationship among the work and PE RVU components in the aggregate, CMS does not anticipate it will affect the distribution of PE RVUs across specialties.

Indirect Cost PE RVUs

Historically, CMS has used the specialties that furnish the service in the most recent full year of Medicare claims data (crosswalked to the current year set of codes) to determine which specialties furnish individual procedures. For example, for CY 2015 ratesetting, CMS used the mix of specialties that furnished the services in the CY 2013 claims data to determine the specialty mix assigned to each code. While CMS believes that there are clear advantages to using the most recent available data in making these determinations, they have also found that using a single year of data contributes to greater year-to-year instability in PE RVUs for individual codes and often creates extreme, annual fluctuations for low-volume services, as well as delayed fluctuations for some services described by new codes once claims data for those codes becomes available. CMS believes that 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 MPFS codes, and for new and low-volume codes in particular. Therefore, CMS is proposing to refine this step of the PE methodology to use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code.

Equipment Maintenance Costs

CMS raised the issue of equipment maintenance costs in the 2015 rulemaking cycle. They received several comments about variable maintenance costs, and in reviewing the information offered in those comments, they believe it is clear that the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment. However, based on their review of comments, CMS was unable to identify a systematic way of varying the maintenance cost assumption relative to the price or useful life of equipment. Therefore, in order to accommodate a variable, as opposed to a standard, maintenance rate within the equipment cost per minute calculation, CMS believes they would have to gather and maintain valid data on the maintenance costs for each equipment item in the direct PE input database, much like they do for price and useful life. Given longstanding difficulties in acquiring accurate pricing...
information for equipment items, CMS is seeking comment on whether adding another item-specific financial variable for equipment costs will be likely to increase the accuracy of PE RVUs across the MPFS.

**Clinical Labor Tasks Associated with Digital Imaging (Page 45)**

In MPFS rulemaking for CY 2015, CMS noted that the RUC recommendation regarding inputs for digital imaging services indicated that, as each code is reviewed under the misvalued code initiative, the clinical labor tasks associated with digital technology (instead of film) would need to be addressed. When CMS reviewed that recommendation, they did not have the capability of assigning standard clinical labor times for the hundreds of individual codes since the direct PE input database did not previously allow for comprehensive adjustments for clinical labor times based on particular clinical labor tasks. Therefore, consistent with the recommendation, CMS proposed to remove film-based supply and equipment items but maintain clinical labor minutes that were assigned based on film technology.

CMS believes it would be appropriate to establish standard times for clinical labor tasks associated with all digital imaging for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the database facilitate their ability to adjust time for existing services. *Therefore, they are seeking comment on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology, which are listed in Table 5 (below).* They note that the application of any standardized times they adopt for clinical labor tasks to codes that are not being reviewed in this proposed rule would be considered for possible inclusion in future notice and comment rulemaking.

<table>
<thead>
<tr>
<th>TABLE 5: Clinical Labor Tasks Associated with Digital Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Labor Task</td>
</tr>
<tr>
<td>Availability of prior images confirmed</td>
</tr>
<tr>
<td>Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocled by radiologist.</td>
</tr>
<tr>
<td>Technologist QC’s* images in PACS, checking for all images, reformats, and dose page.</td>
</tr>
<tr>
<td>Review examination with interpreting MD</td>
</tr>
<tr>
<td>Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.</td>
</tr>
</tbody>
</table>

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

**Clinical Labor Input Inconsistencies (Page 49)**

Subsequent to the publication of the CY 2015 MPFS final rule with comment period, CMS was alerted by stakeholders to several clerical inconsistencies in the clinical labor nonfacility
intraservice time for several vertebroplasty codes with interim final values for CY 2015, based on CMS’s understanding of RUC recommended values. CMS is proposing to correct these inconsistencies in the CY 2016 proposed direct PE input database to reflect the RUC recommended values, without refinement, as stated in the CY 2015 MPFS final rule with comment period.

For CY 2016, CMS is proposing the following adjustments. For CPT codes 22510 (percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic) and 22511 (percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral), a value of 45 minutes for labor code L041B (“Radiologic Technologist”) CMS is proposing to assign for the “assist physician” task and a value of 5 minutes for labor code L037D (“RN/LPN/MTA”) for the “Check dressings & wound/ home care instructions /coordinate office visits /prescriptions” task. For CPT code 22514 (percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar), CMS is proposing to adjust the nonfacility intraservice time to 50 minutes for L041B, 50 minutes for L051A (“RN”), 38 minutes for a second L041B, and 12 minutes for L037D.

Potentially Misvalued Services (Page 64)

RVU Validation Projects

An interim report from the Urban Institute is posted on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban Interim Report.pdf. A final report will be available once the project is complete.

Identification of Potentially Misvalued Codes for CY 2016: Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or More (Page 74)

CMS is proposing 118 codes listed in Table 8 as potentially misvalued codes, identified using the high expenditure screen under the statutory category, “codes that account for the majority of spending under the MPFS.” To develop this list, CMS identified the top 20 codes by specialty in terms of allowed charges. As was done last year, CMS excluded codes that have been reviewed since CY 2010, those with fewer than $10 million in allowed charges, and those that describe anesthesia or E/M services. CMS excluded E/M services from the list of proposed potentially misvalued codes for the same reasons that they were excluded in a similar review in CY 2012. CMS also excluded all codes with 10- and 90-day global periods since CMS believes these codes should be reviewed as part of the global surgery revaluation. Below is a list of radiology codes contained in Table 8.
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Short Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>10022</td>
<td>Fna w/image</td>
</tr>
<tr>
<td>20550</td>
<td>Inj tendon sheath/ligament</td>
</tr>
<tr>
<td>27370</td>
<td>Injection for knee x-ray</td>
</tr>
<tr>
<td>31500</td>
<td>Insert emergency airway</td>
</tr>
<tr>
<td>36215</td>
<td>Place catheter in artery</td>
</tr>
<tr>
<td>36556</td>
<td>Insert non-tunnel cv cath</td>
</tr>
<tr>
<td>36569</td>
<td>Insert picc cath</td>
</tr>
<tr>
<td>36620</td>
<td>Insertion catheter artery</td>
</tr>
<tr>
<td>38221</td>
<td>Bone marrow biopsy</td>
</tr>
<tr>
<td>51700</td>
<td>Irrigation of bladder</td>
</tr>
<tr>
<td>51702</td>
<td>Insert temp bladder cath</td>
</tr>
<tr>
<td>52000</td>
<td>Cystoscopy</td>
</tr>
<tr>
<td>55700</td>
<td>Biopsy of prostate</td>
</tr>
<tr>
<td>70491</td>
<td>Ct soft tissue neck w/dye</td>
</tr>
<tr>
<td>70543</td>
<td>Mri orbit/fac/neck w/o&amp;w/dye</td>
</tr>
<tr>
<td>70544</td>
<td>Mr angiography head w/o dye</td>
</tr>
<tr>
<td>70549</td>
<td>Mr angiograph neck w/o&amp;w/dye</td>
</tr>
<tr>
<td>71010</td>
<td>Chest x-ray 1 view frontal</td>
</tr>
<tr>
<td>71020</td>
<td>Chest x-ray 2vw frontal&amp;latl</td>
</tr>
<tr>
<td>71260</td>
<td>Ct thorax w/dye</td>
</tr>
<tr>
<td>71270</td>
<td>Ct thorax w/o &amp; w/dye</td>
</tr>
<tr>
<td>72195</td>
<td>Mri pelvis w/o dye</td>
</tr>
<tr>
<td>72197</td>
<td>Mri pelvis w/o &amp; w/dye</td>
</tr>
<tr>
<td>73110</td>
<td>X-ray exam of wrist</td>
</tr>
<tr>
<td>73130</td>
<td>X-ray exam of hand</td>
</tr>
<tr>
<td>73718</td>
<td>Mri lower extremity w/o dye</td>
</tr>
<tr>
<td>73720</td>
<td>Mri lwr extremity w/o&amp;w/dye</td>
</tr>
<tr>
<td>74000</td>
<td>X-ray exam of abdomen</td>
</tr>
<tr>
<td>74022</td>
<td>X-ray exam series abdomen</td>
</tr>
<tr>
<td>74181</td>
<td>Mri abdomen w/o dye</td>
</tr>
<tr>
<td>74183</td>
<td>Mri abdomen w/o &amp; w/dye</td>
</tr>
<tr>
<td>75635</td>
<td>Ct angio abdominal arteries</td>
</tr>
<tr>
<td>75710</td>
<td>Artery x-rays arm/leg</td>
</tr>
<tr>
<td>75978</td>
<td>Repair venous blockage</td>
</tr>
<tr>
<td>76512</td>
<td>Opth us b w/non-quant a</td>
</tr>
<tr>
<td>76519</td>
<td>Echo exam of eye</td>
</tr>
<tr>
<td>76536</td>
<td>Us exam of head and neck</td>
</tr>
<tr>
<td>77059</td>
<td>Mri both breasts</td>
</tr>
<tr>
<td>77263</td>
<td>Radiation therapy planning</td>
</tr>
<tr>
<td>77334</td>
<td>Radiation treatment aid(s)</td>
</tr>
</tbody>
</table>
Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure (Page 77)

In the CY 2015 MPFS proposed rule, CMS noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. Due to the changing nature of medical practice, CMS considered establishing a uniform approach to valuation for all Appendix G services. CMS continues to seek an approach that is based on using the best available objective information about the provision of moderate sedation broadly, rather than merely addressing this issue on a code-by-code basis using RUC survey data when individual procedures are revalued. CMS sought public comment on approaches to address the appropriate valuation of these services given that moderate sedation is no longer inherent for many of these services. To the extent that Appendix G procedure values are adjusted to no longer include moderate sedation, CMS requested suggestions as to how moderate sedation should be reported and valued, and how to remove from existing valuations the RVUs and inputs related to moderate sedation.

To establish an approach to valuation for all Appendix G services based on the best data about the provision of moderate sedation, CMS notes that they need to determine the extent of the misvaluation for each code. They know that there are standard packages for the direct PE inputs associated with moderate sedation, and they began to develop approaches to estimate how much of the work is attributable to moderate sedation. However, CMS believes that they should seek input from the medical community prior to proposing changes in values for these services, given the different methodologies used to develop work RVUs for the hundreds of services in Appendix G. Therefore, CMS is seeking recommendations from the RUC and other interested stakeholders for appropriate valuation of the work associated with moderate sedation before formally proposing an approach that allows Medicare to adjust payments based on the resource costs associated with the moderate sedation or anesthesia services that are being furnished.

Payment for Global Surgical Packages (Page 80)

CMS notes that Section 523 of The Medicare Access and CHIP Reauthorization Act (MACRA), enacted into law on April 16, 2015, addresses payment for global surgical packages. Section 523(a) adds a new paragraph at section 1848(c)(8) of the Act. Section 1848(c)(8)(A)(i) of the Act prohibits the Secretary from implementing the policy established in the CY 2015 MPFS final rule with comment period that would have transitioned all 10-day and 90-day global surgery packages to 0-day global periods. Section 1848(c)(8)(A)(ii) of the Act provides that
nothing in the previous clause shall be construed to prevent the Secretary from revaluing misvalued codes for specific surgical services or assigning values to new or revised codes for surgical services.

Section 1848(c)(8)(B)(i) of the Act requires CMS to develop through rulemaking a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection shall begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery, as appropriate. This information must be reported on claims at the end of the global period or in another manner specified by the Secretary. Section 1848(c)(8)(B)(ii) of the Act requires that, every 4 years, CMS must reassess the value of this collected information, and allows CMS to discontinue the collection if the Secretary determines that there is adequate information from other sources in order to accurately value global surgical services. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General will audit a sample of the collected information to verify its accuracy.

Section 1848(c)(8)(C) of the Act requires that, 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 MPFS. Section 523(b) of the MACRA adds a new paragraph at section 1848(c)(9) of the Act which authorizes the Secretary, through rulemaking, to delay up to 5 percent of the MPFS payment for services for which a physician is required to report information under section 1848(c)(8)(B)(i) of the Act until the required information is reported.

Since section 1848(c)(8)(B)(i) of the Act, as added by section 523(a) of the MACRA, requires CMS to use rulemaking to develop and implement the process to gather information needed to value surgical services no later than January 1, 2017, CMS is seeking input from stakeholders on various aspects of this task. They are soliciting comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished by the practitioner reporting the procedure code during the current post-operative periods) needed to increase the accuracy of the values for surgical services. CMS is also seeking comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, they seek information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the post-operative period, and how they 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.

Section 1848(c)(8)(C) of the Act mandates that CMS use the collected data to improve the accuracy of valuation of surgery services beginning in 2019. CMS is seeking public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre and post-operative care, including the follow-up care during post-operative days. CMS is particularly interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. For example, they seek information from stakeholders on whether
(both qualitatively and quantitatively) postoperative visits differ from other E/M services. They are also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during post-operative care. CMS believes that stakeholder input regarding these questions will help determine what data should be collected, as well as how to improve the accuracy of the valuations. CMS intends to provide further opportunities for public feedback prior to developing a proposal for CY 2017 to collect this required data. CMS also seeks comments regarding stakeholder interest in the potential for an open door forum, town hall meetings with the public, or other avenues for direct communication regarding implementation of these provisions of the Act.

Refinement Panel (Page 84)

Beginning in CY 2016, CMS is proposing to permanently eliminate the refinement panel and instead publish the proposed rates for all interim final codes in the MPFS proposed rule for the subsequent year.

As explained in the CY 2015 final rule with comment period, only a small number of codes being valued for CY 2016 will be published as interim final in the 2016 MPFS final rule with comment period and be subject to comment. CMS will evaluate the comments they receive on these code values, and both respond to these comments and propose values for these codes for CY 2017 in the CY 2017 MPFS proposed rule. Therefore, CMS points out that stakeholders will have two opportunities to comment and to provide any new clinical information that was not available at the time of the RUC valuation that might affect work RVU values that are adopted on an interim final basis. CMS believes that this proposed process, which includes two opportunities for public notice and comment, offers stakeholders a better mechanism and ample opportunity for providing any additional data for our consideration, and discussing any concerns with the interim final values, than the current refinement process. It also provides greater transparency because comments on the rules are made available to the public at www.regulations.gov. CMS welcomes comments on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

Valuation of Specific Codes (Page 114)

In the CY 2015 MPFS final rule with comment period, CMS finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, CMS includes proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. CY 2016 represents a transition year for this new process. For CY 2016, CMS is proposing new values in the proposed rule for the codes for which they received complete RUC recommendations 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 this proposed rule, CMS will establish interim final values in the final rule with comment period, consistent with previous practice. CMS notes that they will consider all comments received in response to proposed values for codes in this rule, including alternative recommendations to those used in developing the proposed rule. In other words, if the RUC or other interested stakeholders submit public comments that include new recommendations for codes for which CMS proposes values as part
of this proposed rule, they would consider those recommendations in developing final values for the codes in the CY 2016 MPFS final rule with comment.

Proposed Values for New, Revised, and Potentially Misvalued CPT Codes

CMS details proposed work RVUs for new, revised and potentially misvalued CPT codes in Tables 11 (beginning on page 131). For PE input recommendations, CMS lists those codes whose RUC recommendations were accepted without refinement in Table 12 (beginning on page 139) and those codes that have proposed refinements in Table 13 (beginning on page 141). Of the codes presented to the RUC by the ACR, CMS accepted approximately 60 percent of the RUC approved values. ACR staff and physician volunteers are conducting a thorough review and analysis of the codes related to radiology.

CMS provides rationale for some RVU refinements, which are detailed below.

Radiation Treatment and Related Image Guidance Services (Page 233)

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. CMS identified these codes as potentially misvalued under a screen called “Services with Stand-Alone PE Procedure Time.” CMS proposed this screen following our discovery of significant discrepancies between the RUC-recommended 60 minute procedure time assumptions for intensity modulated radiation therapy (IMRT) and information available to the public suggesting that the procedure typically took between 5 and 30 minutes per treatment.

The CPT Editorial Panel’s revisions included the addition and deletion of several codes and the development of new guidelines and coding instructions. Four treatment delivery codes (77402, 77403, 77404, and 77406) were condensed into 77402 (Radiation Treatment Delivery, Simple), three treatment delivery codes (77407, 77408, 77409) were condensed into 77407 (Radiation treatment delivery, intermediate), and four treatment codes (77412, 77413, 77414, 77416) were condensed into 77412 (Radiation treatment delivery, complex). Intensity Modulated Radiation Therapy (IMRT) treatment delivery, previously reported under a single code, was split into two codes, 77385 (IMRT treatment delivery, simple) and 77386 (IMRT treatment delivery, complex). The CPT Editorial Panel also created a new image guidance code, 77387 (Guidance for localization of target volume for delivery of treatment, includes intrafraction tracking when performed) to replace 77014 (computed tomography guidance for placement of radiation therapy fields), 77421 (stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy,) and 76950 (ultrasonic guidance for placement of radiation therapy fields) when any of these services were furnished in conjunction with radiation treatment delivery.

In response to stakeholder concerns, CMS delayed implementation of the new code set until 2016 and instead created G-codes that mimicked the predecessor CPT codes. In the CY 2016 proposed rule, CMS proposes to establish values for the new codes based on RUC recommendations, subject to standard CMS refinements that appear in Table 15 of the proposed rule. CMS also notes that because the invoices used to price the capital equipment included “onboard imaging,” the cost of that equipment is already reflected in the price per minute.
associated with the capital equipment. Therefore, CMS has not included it as a separate item in the proposed direct PE inputs for these codes, even though it appeared as a separate item on the PE worksheet included with the RUC recommendations for these codes.

In addition to the refinements addressed above, there are three additional issues for which CMS is seeking comment and/or making specific proposals related to these services: image guidance, equipment utilization rate assumptions for linear accelerators, and superficial radiation treatment services.

1) Image Guidance Services

Under the previous CPT coding structure, image guidance was separately billable when furnished in conjunction with the radiation treatment delivery services. The image guidance was reported using different CPT codes, depending on which image guidance modality was used. In the revised coding structure, one new image guidance code is to be reported regardless of the modality used, and in developing its recommended values, the RUC assumed that CT guidance would be typical.

However, the 2013 Medicare claims data for separately reported image guidance indicates that stereotactic guidance for radiation treatment services was furnished more frequently than CT guidance. The RUC has recommended a work RVU of 0.58 and associated work times of 3 pre-service minutes, 10 intraservice minutes, and 3 post-service minutes for image guidance CPT code 77387. CMS reviewed this recommendation considering the discrepancy between the modality the RUC assumed to be typical in the vignette and the modality typically reported in the Medicare claims data. Given that the recommended work RVU for the new single code is similar to the work RVUs of the predecessor codes, roughly prorated based on their distribution in Medicare claims data, CMS agrees with the RUC recommended work RVU for the service. However, the RUC also recommended an increase in overall work time associated with image guidance consistent with the survey data used to value the new services. If accurate, this increase in time and maintenance of total work would suggest a decrease in the overall intensity for image guidance relative to the current codes. Given this implication, CMS is seeking comment as to the appropriate work time associated with CPT code 77387.

Although 77421 (stereotactic guidance) and 76950 (ultrasonic guidance) have been deleted, CMS notes that CPT maintained CPT code 77014 (Computed tomography guidance for placement of radiation therapy fields) and the RUC recommendation states that CPT did so based on concerns that without this option, some practitioners might have no valid CPT alternative than to use higher valued diagnostic CT codes when they used this CT guidance. The RUC recommendation also includes a statement that utilization of this code is expected to drop to negligible levels by 2015, assuming that practitioners would use the new codes that are not differentiated based on imaging modality. Once all the new codes are implemented for Medicare, CMS anticipates that CPT and/or the RUC will address the continued use of 77014 and, if it continues to be part of the code set, provide recommendations as to the appropriate values given changes in utilization.
Regarding the reporting of the new image guidance codes, CPT guidance instructs that the technical portion of image guidance is now bundled into the IMRT and Stereotactic Radiation Treatment delivery codes, but it is not bundled into the simple, intermediate, and complex radiation treatment delivery codes. CPT guidance states that the technical component of the image guidance code can be reported with codes 77402, 77407, and 77412 (simple, intermediate, and complex radiation treatment) when furnished, which means that the technical component of the image guidance code should not be reported with the IMRT or Stereotactic Radiation Treatment delivery codes. The RUC recommendation, however, incorporates the same capital cost of image guidance equipment (a linear accelerator, or linac), for all these radiation treatment delivery codes, including the codes that describe IMRT and Stereotactic Radiation Treatment delivery services. The RUC explains that the recommendations were done this way because the older lower-dose external beam radiation machines are no longer manufactured and the image guidance technology is integrated into the single kind of linear accelerator used for all the radiation treatment services. In reviewing the new code structure and the RUC recommendations, CMS assumes that the CPT editorial panel did not foresee that the RUC would recommend that they develop PE RVUs for all the radiation treatment delivery codes based on the assumption that the same capital equipment is typically used in furnishing the entire range of external beam radiation treatments. Because the RUC recommendations incorporate the more extensive capital equipment in the lower dose treatment codes as well, a portion of the resource costs of the technical portion of imaging guidance are already allocated into the PE RVUs for all of the treatment delivery codes, not just the IMRT and Stereotactic Radiation Treatment delivery codes as CPT guidance would suggest.

In order to avoid incorporating the cost of this equipment into both the treatment delivery codes (77402, 77407, and 77412) and the technical component of the new imaging guidance code (77387-TC), CMS considered valuing 77387 as a professional service only and not creating the professional/technical component splits envisioned by CPT. In the context of the budget neutral MPFS, incorporating a duplicative direct input with a cost of more than six dollars per minute has significant impacts on the PE RVUs for all other services. However, CMS also noted that the RUC did not address this apparent contradiction in its recommendation and not all of the recommended direct PE inputs for the technical component of 77387 are capital equipment costs. Therefore, CMS is proposing to allow for professional and technical component billing for these services, as reflected in CPT guidance, and they are proposing to use the RUC recommended direct PE inputs for these services (refined as described in Table 15). However, they are also seeking comment on the apparent contradiction between technical component billing for image guidance in the context of the inclusion of a single linac with integrated imaging guidance technology being included for all external beam treatment codes.

2) Equipment Utilization Rate for Linear Accelerators

Based on the RUC recommendations for the new codes that describe radiation treatment services, CMS does not believe the default assumptions regarding equipment usage are accurate for the capital equipment used in radiation treatment services. The RUC recommendations assume that the same type of linear accelerator is now typically used to furnish all levels and types of external beam radiation treatment services because the machines previously used to
furnish these services are no longer manufactured. In valuing the previous code set and making procedure time assumptions, different equipment items were assumed to be used to furnish the different levels and types of radiation treatment. With the current RUC recommended inputs, CMS can then assume that the same equipment item is used to furnish more services. If it is assumed the RUC recommendation to include the same kind of capital equipment for all of these codes is accurate, CMS believes that it is illogical to continue to assume that the equipment is only used for 25 out of a possible 50 hours per week. In order to estimate the difference between the previous number of minutes the linear accelerator was assumed to be in use under the previous valuation and the number of minutes now being recommended, CMS applied the change in assumptions to the services reported in the most recent year of Medicare claims data. Under the assumptions reflected in the previous direct PE inputs, the kind of linear accelerator used for IMRT made up a total of 44.8 million out of 65 million minutes of external beam treatments furnished to Medicare beneficiaries. Under the new code set, however, a single kind of linear accelerator would be used for all of the 65 million minutes furnished to Medicare beneficiaries. This represents a 45 percent increase in the aggregate amount of time that this kind of linac is in use. Of course, the utilization rate that corresponds with that increase in minutes is not necessarily precise since the current utilization rate only reflects the default assumption and is not itself rooted in empirical data. Additionally, in some cases, individual practices that already use linear accelerators for IMRT may have replaced the now-obsolete capital equipment with new, additional linear accelerators instead of increasing the use of capital equipment already owned. However, CMS does not believe that the latter scenario is likely to be common in cases where the linear accelerators had previously been used only 25 hours per week.

Therefore, CMS is proposing to adjust the equipment utilization rate assumption for the linear accelerator to account for the significant increase in usage. Instead of applying the default 50 percent assumption, they are proposing to use a 70 percent assumption based on the recognition that the item is now being typically used in a significantly broader range of services, and that would increase its overall usage in comparison to the previous assumption. CMS notes that they developed the 70 percent rate based on a rough reconciliation between the number of minutes the equipment is being used according to the new recommendations versus the current number of minutes based on an analysis of claims data. CMS continues to seek evidence to ensure that the usage assumptions, both the utilization rate and number of available hours, used to calculate equipment costs are as accurate as possible.

CMS believes that comparing the changes in direct PE input recommendations and using the Medicare claims data indicates that the utilization assumption to 70 percent is more accurate than the default utilization assumption of 50 percent. However, they have reviewed other information that suggests this utilization rate may be higher than 70 percent and that the number of available hours per week is greater than 50.

For example, as part of the 2014 RUC recommendations for the Radiation Treatment Delivery codes, the RUC submitted a 2011 staffing survey conducted by the American Society for Radiology Technicians (ASRT). Using the 2014 version of the same study, CMS noted that there are an average of 2.3 linacs per radiation treatment facility and 52.7 patients per day treated per radiation treatment facility. These data suggest that an average of 22.9 patients is treated on each linac per day. Using an average of the RUC-recommended procedure times for CPT codes
77385, 77386, 77402, 77407, and 77412 weighted by the annual volume of procedures derived from Medicare claims data yielded a total of 670.39 minutes or 11.2 hours that a single linac is in use per day. This is in contrast to both the number of hours of use reflected in the default assumptions (5 of the 10 available business hours per day) and in the proposed revision to the equipment utilization rate assumption (7 hours out of 10 available business hours per day).

Given the fact that it is likely that the transition to the linear accelerator began prior to the 2013 reevaluation of the radiation treatment delivery codes by CPT and that the useful life of the newest generation of linear accelerator is 7 years, CMS believes a 2-year transition to the 70 percent utilization rate assumption would account for any remaining time to transition to the new equipment. Therefore, in developing PE RVUs for these services, CMS is proposing to use a 60 percent utilization rate assumption for CY 2016 and a 70 percent utilization rate assumption for CY 2017. Additionally, CMS continues to seek empirical data on the capital equipment costs, including equipment utilization rates, for the linac and other capital-intensive machines, and seeks comment on how to most accurately address issues surrounding those costs within the PE methodology.

3) Superficial Radiation Treatment Delivery

In the CY 2015 MPFS final rule with comment period, CMS noted that changes to the CPT prefatory language modify the services that are appropriately billed with CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other procedures supporting superficial radiation therapy were bundled with 77401. The RUC, however, did not review the inputs for superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. In the CY 2015 MPFS final rule with comment period, CMS requested information on whether the new radiation therapy code set combined with modifications in prefatory text allowed for appropriate reporting of the services associated with superficial radiation and whether the payment continued to reflect the relative resources required to furnish superficial radiation therapy services.

In response to the request, CMS received a recommendation from a stakeholder to make adjustments to both the physician work and PE components for code 77401. The stakeholder suggested that since crucial aspects of the service, such as treatment planning and device design and construction, were not currently reflected in 77401, and practitioners were precluded from reporting these activities separately, that physician work should be included for CPT code 77401. Additionally, the stakeholders suggested that the current inputs used to value the code are not accurate because the inputs include zero physician work and minutes for a radiation therapist to provide the service directly to the patient. The stakeholders suggested, alternatively, that physicians, not radiation therapists, typically provide superficial radiation services directly. Therefore, CMS is seeking recommendations from other stakeholders, including the RUC, regarding whether or not it would be appropriate to add physician work for this service and remove minutes for the radiation therapists, even though physician work is not included in other radiation treatment services.
The stakeholder also suggested that CMS amend the direct PE inputs by including nurse time and updating the price of the capital equipment used in furnishing the service. CMS believes it would be most appropriate to address the clinical labor assigned to the code in the context of the information regarding the physician work that might be associated with the service. Therefore, CMS seeks information on the possible inclusion of nurse time for this service as part of the comments and/or recommendations regarding physician work for the service. However, CMS reviewed the submitted invoices for the request to update the capital equipment for the service. They are proposing to update the equipment item ER045 “orthovoltage radiotherapy system” by renaming it “SRT-100 superficial radiation therapy system” and updating the price from $140,000 to $216,000, on the basis of the submitted invoices.

Endobronchial Ultrasound (CPT Codes 31622, 3160A, 3160B, 31625, 31626, 31628, 31629, 3160C, 31632 and 31633) (Page 249)

For CY 2016, the CPT Editorial Panel deleted one code, CPT 31620 (Ultrasound of lung airways using an endoscope), and created three new codes, CPT 3160A-3160C, to describe bronchoscopic procedures that are inherently performed with endobronchial ultrasound (EBUS).

In their review of the newly revised EBUS family, the RUC recommended a change in the work RVU for CPT code 31629 from 4.09 to 4.00. The RUC also recommended maintaining the current work RVUs for CPT codes 31622, 31625, 31626, 31628, 31632 and 31633. CMS is proposing to use those values for CY 2016.

For the newly created codes, the RUC recommended a work RVU of 5.00 for CPT code 3160A, 5.50 for CPT code 3160B and 1.70 for CPT code 3160C. CMS believes the recommended work RVUs for these services overstate the work involved in furnishing the procedures. In order to develop proposed work RVUs for CPT code 3160A, CMS compared the service described by the new code to deleted CPT codes 31620 and 31629, because this new code describes a service that combines services described by 31620 and 31629. Specifically, CMS took the sum of the current work RVU of CPT code 31629 (WRVU=4.09) and the CY 2015 work RVU of CPT code 31620 (WRVU=1.40) and multiplied it by the quotient of CPT code 3160A’s RUC-recommended intraservice time (INTRA=60 min) and the sum of CPT codes 31620 and 31629’s current and CY 2015 intraservice times (INTRA=70 min), respectively. This resulted in a work RVU of 4.71 and CMS is proposing that value. To value CPT code 3160B, CMS used the RUC recommended increment of 0.5 work RVU between this service and CPT code 3160A to calculate for CPT code 3160B the proposed work RVUs of 5.21. Lastly, because the service described by new CPT code 3160C is very similar to deleted CPT code 31620, CMS believes a direct crosswalk of the previous values for 31620 accurately reflects the time and intensity of furnishing the service described by 3160C. Therefore, CMS is proposing a work RVUs of 1.40 for CPT code 3160C.


For CY 2016, the CPT Editorial Panel is deleting six codes (50392, 50393, 50394, 50398,
that were commonly reported together, and are creating 12 new codes both to
describe these genitourinary catheter procedures more accurately and to bundle inherent imaging
services. Three of these codes (506XF, 507XK, and 507XL) were referred back to CPT to be
resurveyed as add-on codes. The other nine codes were reviewed at the January 2015 RUC
meeting and assigned recommended work RVUs and direct PE inputs.

1) Work RVUs

**CMS is proposing to use the RUC-recommended work RVU of 3.15 for CPT code 5039A.**

They agree that this is an appropriate value, and that the code should be used as a basis for
establishing relativity with the rest of the family. As a result, CMS began by making
comparisons between the service times of CPT code 5039A and the other codes in the family in
order to determine the appropriate proposed work value of each procedure.

For CPT code 5039B, CMS disagrees with the RUC recommended work RVU of 1.42, and they
are instead proposing a work RVU of 1.10, based on three separate data points. First, the RUC
summary of recommendations stated that CPT code 5039B describes work previously described
by a combination of CPT codes 50394 and 74425. These two codes have work RVUs of 0.76 and
0.36, respectively, which sum together to 1.12. Second, CMS noted that the work of CPT code
49460 (Mechanical removal of obstructive material from gastrostomy) is similar, with the same
intraservice time of 15 minutes and same total time of 55 minutes but a work RVU of 0.96.
Finally, CMS observed that the minimum survey result had a work RVU of 1.10, and they
believe this value appropriately reflects the total work for the service. Accordingly, **CMS is
proposing 1.10 as the work RVU for CPT code 5039B.**

CMS employed a similar methodology to develop a proposed work RVU of 4.25 for CPT code
5039C. The three previously established codes are being combined in CPT code 5039C; these
had respective work values of 3.37 (CPT code 50392), 0.54 (CPT code 74475), and 0.36 (CPT
code 74425); together these sum to 4.27 work RVUs. CMS also looked at valuing CPT code
5039C based on relativity with other codes in the family. The ratio of the intraservice time of 35
minutes for CPT code 5039A and the intraservice time of 48 minutes for CPT code 5039C;
applied to the work RVU of base code 5039A (3.15) results in a potential work RVU of 4.32.
The total time compared to CPT code 5039A also went from 91 minutes to 107 minutes and this
ratio applied to the base work RVU results in a work RVU of 3.70. CMS utilized these data to
inform their choice of an appropriate crosswalk. They believe CPT code 31660 (Bronchoscopy,
rigid or flexible, including fluoroscopic guidance) is an appropriate reference crosswalk for CPT
code 5039C. CPT code 31660 has an intraservice time of 50 minutes, total time of 105 minutes,
and a work RVU of 4.25. **Therefore, CMS proposes to establish the work RVU for CPT code
5039C at the crosswalked value of 4.25 work RVUs.**

According to the RUC recommendations, CPT codes 5039C and 5039D are very similar
procedures, with CPT code 5039D making use of a nephroureteral catheter instead of a
nephrostomy catheter. The RUC valued the added difficulty of CPT code 5039D at 1.05 work
RVUs compared to code CPT code 5039C. CMS is maintaining the relative difference in work
between these two codes by proposing a value of 5.30 for CPT code 5039D. (This is the work
RVU of 4.25 for CPT code 5039C plus 1.05 RVUs.) Additionally, CMS is using CPT code
57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy) as their reference crosswalk. **CPT code 57155 has a work RVU of 5.40 and an identical intraservice time of 60 minutes, but it also has fourteen additional minutes of total time, 133 minutes compared to 119 minutes for CPT code 5039D, which supports the difference of 0.10 RVUs. For these reasons, CMS is proposing the value of CPT code 5039D at 5.30 work RVUs.**

As with the other genitourinary codes, CMS developed the proposed work value of CPT code 5039M in order to preserve relativity within the family. CPT code 5039M has 15 fewer minutes of intraservice time compared to CPT code 5039D (45 minutes compared to 60 minutes). This is a ratio of 0.75, applied to the based work RVU of CPT code 5039D (5.30) resulted in a potential work RVU of 3.98. CPT code 5039C was another close match within the family, with 3 more minutes of intraservice time compared to 5039M, 48 minutes of intraservice time instead of 45 minutes. This ratio (0.94) applied to the base work RVU of CPT code 5039C (4.25) also resulted in a potential work RVU of 3.98. Based on this information, **CMS identified CPT code 31634 (Bronchoscopy, rigid or flexible, with balloon occlusion) as an appropriate crosswalk, and proposes a work RVU of 4.00 for CPT code 5039M.** The two codes share an identical intraservice time of 45 minutes, though the latter possesses a lower total time of 90 minutes.

For CPT code 5039E, CMS considered how the code and work RVU would fit within the family in comparison to the proposed values for CPT codes 5039A and 5039C. CPT code 5039A serves as the base code for this group; it has 35 minutes of intraservice time in comparison to 20 minutes for CPT code 5039E. This intraservice time ratio of 0.57 resulted in a potential work RVU of 1.80 for CPT code 5039E when applied to the work RVU of CPT code 5039A (3.15). Similarly, CPT code 5039C is the most clinically similar procedure to CPT code 5039E. CPT code 5039C has 48 minutes of intraservice time compared to 20 minutes of intraservice time for CPT code 5039E. This ratio of 0.42 applied to the base work RVU of CPT code 5039C (4.25) results in a potential work RVU of 1.77. CMS also made use of two crosswalks to help determine a proposed value for CPT code 5039E. CPT code 64416 (Injection, anesthetic agent; brachial plexus) also includes 20 minutes of intraservice time and has a work RVU of 1.81. CPT code 36569 (Insertion of peripherally inserted central venous catheter) has the same intraservice and total time as CPT code 5039E, with a work RVU of 1.82. Accordingly, **CMS is crosswalking the work RVU for CPT code 5039E to CPT code 36569 and proposing a work RVU of 1.82 for CY 2016.**

The remaining three codes all utilize ureteral stents and form their own small subfamily within the larger group of genitourinary catheter procedures. **For CPT code 5069G, CMS is proposing a work RVU of 4.21, which is the 25th percentile result from the survey information.** CMS believes that the 25th percentile provides a more accurate value for CPT code 5069G based on the work involved in the procedure and within the context of other codes in the family. They are also referencing CPT code 31648 (Bronchoscopy, rigid or flexible, with removal of bronchial valve), which shares 45 minutes of intraservice time and has a work RVU of 4.20, as an appropriate crosswalk for CPT code 5069G.

For CPT code 5069H, CMS compared its intraservice time to the code within the family that had the most similar duration, CPT code 5039D. This code has 60 minutes of intraservice time compared to 62 minutes for CPT code 5069H. This is a ratio of 1.03 applied to the base work
RVU of CPT code 5039D (5.30) resulted in a potential work RVU of 5.48. CMS also looked to crosswalks with similar numbers, in particular CPT code 50382 (Removal and replacement of internally dwelling ureteral stent). This code has 60 minutes of intraservice time, 125 minutes of total time, and a work RVU of 5.50. For these reasons, CMS is crosswalking CPT code 5069H to CPT code 50382 and proposing a work RVU of 5.50.

Finally, CMS developed the proposed value for CPT code 5069I using three related methods. CPT codes 5069H and 5069I describe very similar procedures, with 5069I adding the use of a nephrostomy tube. The RUC addressed the additional difficulty of this procedure by recommending 1.55 more work RVUs for CPT code 5069I than for CPT code 5069H. Adding the 1.55 work RVUs to the proposed work RVU for CPT code 5069H (5.50) would produce a work RVU of 7.05 for CPT code 5069I. CMS also looked at the ratio of intraservice times for CPT code 5069I (75 minutes) and the base code in the subfamily, CPT code 5069G (45 minutes). The intraservice time ratio between these two codes is 1.67 when applied to the base work RVU of CPT code 5069G (4.21) resulted in a potential work RVU of 7.02. CMS also identified an appropriate crosswalk reference in CPT code 36481 (Percutaneous portal vein catheterization by any method) which shares the same intraservice time as CPT code 5069I and has a work RVU of 6.98. Accordingly, to maintain relativity among this subfamily of codes, CMS is proposing a work RVU of 7.05 for CPT code 5069I based on an incremental increase of 1.55 RVUs from CPT code 5069H.

2) Practice Expense Inputs

In reviewing the direct PE inputs for this family of codes, CMS refined a series of the RUC recommended inputs in order to maintain relativity with current standards. All of the following refinements refer to the non-facility setting for this family of codes. Under the clinical labor inputs, CMS is proposing to remove the RN/LPN/MTA (L037D) (intraservice time for assisting physician in performing procedure) for CPT codes 5039B and 5039E. This amounts to 15 minutes for CPT code 5039B and 20 minutes for CPT code 5039E. Moderate sedation is not inherent in these procedures and, therefore, CMS does not believe that this clinical labor task would typically be completed in the course of this procedure. They are also reducing the RadTech (L041B) intraservice time for acquiring images from 47 minutes to 46 minutes for CPT code 5069H. This procedure contains 62 minutes of intraservice time, with clinical labor assigned for acquiring images (75 percent) and a circulator (25 percent). The exact time for these clinical labor tasks multiplies out to 46.5 minutes and 15.5 minutes, respectively. The RUC recommendation for CPT code 5069H rounded both of these values upwards, assigning 47 minutes for acquiring images and 16 minutes for the circulator, which together sum to 63 minutes. CMS is reducing the clinical labor time for acquiring images to 46 minutes to preserve the 62 minutes of total intraservice time for CPT code 5069H.

During the post-service portion of the clinical labor service period, CMS is proposing to change the labor type for the “patient monitoring following service/check tubes, monitors, drains (not related to moderate sedation)” input. There are 45 minutes of clinical labor time assigned under this category to CPT codes 5039A, 5039C, 5039D, 5039M, 5069G, 5069H, and 5069I. Although CMS agrees that the 45 minutes are appropriate for these procedures as part of moderate sedation, they are changing the clinical labor type from the recommended RN (L051A) to
RN/LPN/MTA (L037D) to reflect the staff that will typically be doing the monitoring for these procedures. Even though the CPT Editorial Committee’s description of post-service work for CPT code 5039E includes a recovery period for sedation, CMS recognizes that according to the recommendation, CPT codes 5039B and 5039E do not use moderate sedation, so they did not propose to include moderate sedation inputs for these codes.

The RUC recommendation for CPT code 5039D includes a nephroureteral catheter as a new supply input with an included invoice. However, in the RUC summary of recommendations for this code, there is no mention of a nephroureteral catheter in the intraservice work description. CPT code 5039D does mention the use of a nephroureteral stent in this description, but there is no request for a nephroureteral stent supply item on the PE worksheet for this code. **CMS is therefore seeking clarification from stakeholders regarding the use of the nephroureteral catheter for CPT code 5039D. They have not proposed to add the nephroureteral catheter as a supply item for CPT code 5039D pending this information. CMS is also requesting a clarification to the intraservice work description in the summary of recommendations for this code to explain the use, if any, of the nephroureteral catheter in this procedure.**

The RUC recommended the inclusion of “room, angiography” (EL011) for this family of codes. CMS does not agree with the RUC that an angiography room would be used in the typical case for these procedures, as there are other rooms available which can provide fluoroscopic guidance. Most of the codes that make use of an angiography room are cardiovascular codes, and much of the equipment listed for this room would not be used for non-cardiovascular procedures. **CMS is therefore proposing to replace equipment item “room, angiography” (EL011) with equipment item “room, radiographic-fluoroscopic” (EL014) for the same number of minutes. CMS is requesting public comment regarding the typical room type used to furnish the services described by these CPT codes, as well as the more general question of the typical room type used for GU and GI procedures.** In the past, the RUC has developed broad recommendations regarding the typical uses of rooms for particular procedures, including the radiographic-fluoroscopy room. CMS believes that such a recommendation from the RUC concerning all of these codes could be useful in ensuring relativity across the MPFS.

**Spinal Instability (CPT code 7208A, 7208B, 7208C, and 7208D) (Page 262)**

For CY 2015, the CPT Editorial Panel deleted codes 72010 (radiologic examination, spine, entire, survey study, anteroposterior and lateral), 72069 (radiologic examination, spine, thoracolumbar, standing (scoliosis)), and 72090 (radiological examination, spine; scoliosis study, including supine and erect studies), revised one code, 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views) and created four new codes which cover radiologic examination of the entire thoracic and lumbar spine, including the skull, cervical and sacral spine if performed. The new codes were organized by number of views, ranging from one view in 7208A, two to three views in 7208B, four to five views in 7208C, and minimum of 6 views in 7208D.

CMS disagrees with the RUC’s work RVU recommendations for these four codes. For 7208A, CMS noted that the one minute increase in time resulted in a larger work RVU than would be expected when taking the ratio between time and RVU in the source code and comparing that to
the time and work RVU ratio in the new code. Using the relationship between time and RVU from deleted code 72069, CMS is proposing a work RVU of 0.26 for 7208A, which differs from the RUC-recommended value of 0.30. Using an incremental methodology based on the relationship between work and time in the first code they are proposing to adjust the RUC recommended work RVUs for CPT codes 7208B, 7208C and 7208D to, respectively, 0.31, 0.35, and 0.41.

Echo guidance for ova aspiration (CPT code 76948) (Page 263)

In the CY 2014 MPFS final rule with comment period, CMS requested additional information to assist in the valuation of ultrasound guidance codes. They nominated these codes as potentially misvalued based on the extent to which standalone ultrasound guidance codes were billed separately from services where ultrasound guidance was an integral part of the procedure. CPT code 76948 was among the codes considered potentially misvalued. CPT code 76948 was surveyed by the specialty societies and the RUC issued a recommendation for CY 2016. CMS has concerns about the valuation of this code, considering that it is a guidance code used only for a single procedure: 58970 (aspiration of ova), and they believe that these two codes are almost always billed concurrently. CMS believes codes 76948 and 58970 should be bundled to accurately reflect how the service is furnished.

CMS is proposing to use work times based on refinements of the RUC-recommended values by removing the 3 minutes of pre and post service time since these times are reflected in the 58970 procedure code. They are proposing work and time values for 76948 based on a crosswalk from 76945 (Ultrasound guidance for chorionic villus sampling, imaging supervision and interpretation) which has a physician work time of 30 minutes and an RVU of 0.56. Therefore CMS is proposing to maintain 25 minutes of intraservice time for 76948 and proposing a work RVU of 0.56.

Low-dose computer tomography, lung, screening (GXXX1) and lung cancer screening counseling and shared decision making visit (GXXX2) (Page 269)

CMS has issued a national coverage determination (NCD) for the coverage of a lung cancer screening counseling and shared decision making visit and, for appropriate beneficiaries, annual screening with low dose computed tomography (LDCT) as an additional preventive benefit. The ACR submitted recommendations for work and direct PE inputs. The ACR recommended that CMS crosswalk GXXX1 to 71250 (computed tomography, thorax; without contrast material) with additional physician work added to account for the added intensity of the service. After reviewing this recommendation, CMS believes that the physician work (time and intensity) is identical in both GXXX1 and 71250, and therefore, they are proposing a work RVU of 1.02 for GXXX1.

CMS is proposing to value the lung cancer screening counseling and shared decision making visit (GXXX2) using a crosswalk from the work value for G0443 (Brief face-to-face counseling for alcohol misuse, 15 minutes) which has a work RVU of 0.45. They added 2 minutes of pre-service time, and 1 minute post-service time which CMS valued at 0.0224 RVU
per minute yielding a total of 0.062 additional RVUs which they then added to 0.45, bringing the total proposed work RVUs for GXXX2 to 0.52.

**Malpractice RVUs (Page 56)**

For CY 2016, CMS propose to continue their current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which they include proposed work values and PE inputs in the proposed rule, CMS will also publish the proposed MP crosswalks used to determine their MP RVUs in the proposed rule. The MP crosswalks for those new and revised codes will be subject to public comment and finalized in the CY 2016 MPFS final rule. The MP crosswalks for new and revised codes with interim final values established in the CY 2016 final rule will be implemented for CY 2016 and subject to public comment. They will then be finalized in the CY 2017 MPFS final rule with comment period.

**Proposed Annual Update for Malpractice RVUs**

For CY 2016, CMS is proposing to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services, and to adjust MP RVUs for risk. Under this approach, the specialty-specific risk factors would continue to be updated every five years using updated premium data, but would remain unchanged between the 5-year reviews. However, in an effort to ensure that MP RVUs are as current as possible, the proposal would involve recalibrating all MP RVUs on an annual basis to reflect the specialty mix based on updated Medicare claims data. Since under this proposal, CMS would be recalculating the MP RVUs annually, they are also proposing to maintain the relative pool of MP RVUs from year to year; this will preserve the relative weight of MP RVUs to work and PE RVUs. CMS is proposing to calculate the current pool of MP RVUs by using a process parallel to that used in calculating the pool of PE RVUs. To determine the specialty mix assigned to each code, CMS is also proposing to use the same process used in the PE methodology, described in section II.2.b.(6) of this proposed rule. They note that for CY 2016, as described above, CMS is proposing to modify the specialty mix assignment methodology to use an average of the 3 most recent years of available data instead of a single year of data as is the current policy. CMS anticipates that this change will increase the stability of PE and MP RVUs and mitigate code-level fluctuations for all services paid under the MPFS, and for new and low-volume codes in particular. CMS is also proposing to no longer apply the dominant specialty for low volume services, because the primary rationale for the policy has been mitigated by this proposed change in methodology. However, CMS is not proposing to adjust the code-specific overrides established in prior rulemaking for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service. CMS believes that these proposed changes will serve to balance the advantages of using annually updated information with the need for year-to-year stability in values.

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

CMS is also proposing an additional refinement in the process for assigning MP RVUs to individual codes. Historically, they have used a floor of 0.01 MP RVUs for all nationally-priced MPFS codes. This means that even when the code-level calculation for the MP RVU falls below 0.005, CMS has rounded to 0.01. In general, CMS believes this approach accounts for the minimum MP costs associated with each service furnished to a Medicare beneficiary. However, in 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 2 add-on codes, etc. Therefore, CMS is proposing to maintain the 0.01 MP RVU floor for all nationally-priced MPFS services that are described by base codes, but not for add-on codes. They will continue to calculate, display, and make payments that include MP RVUs for add-on codes that are calculated to 0.01 or greater, including those that round to 0.01. CMS is only proposing to allow the MP RVUs for add-on codes to round to 0.00 where the calculated MP RVU is less than 0.005. CMS will continue to study the appropriate frequency for collecting and updating premium data and will address any further proposed changes in future rulemaking.

**MP RVU Methodology Refinements**

CMS is proposing to update the calculation to use a price-adjusted premium (that is, the premium divided by the GPCI) in each area, and then taking a weighted average of those adjusted premiums. The CY 2016 MPFS proposed rule MP RVUs were calculated in this manner.

Additionally, in the calculation of the national average premium for each specialty, the current methodology used the total RVUs in each area as the weight in the numerator (that is, for premiums), and total MP RVUs as the weights in the denominator (that is, for the MP GPCIs). After further consideration, CMS believes that the use of these RVU weights is problematic. Use of weights that are central to the process at hand presents potential circularity since both weights incorporate MP RVUs as part of the computation to calculate MP RVUs. The use of different weights for the numerator and denominator introduces potential inconsistency. Instead, CMS believes that it would be better to use a different measure that is independent of MP RVUs and better represents the reason for weighting. Specifically, CMS is proposing to use area population as a share of total U.S. population as the weight. The premium data are for all MP premium costs, not just those associated with Medicare patients, so CMS believes that the distribution of the population does a better job of capturing the role of each area’s premium in the “national” premium for each specialty than the previous Medicare-specific measure. Use of population weights also avoids the potential problems of circularity and inconsistency. The CY 2016 MPFS proposed MP RVUs, as displayed in Addendum B of this proposed rule, reflect MP RVUs calculated following our established methodology, with the inclusion of the proposals and refinements described above.
Target for Relative Value Adjustments for Misvalued Services (Page 97)

Background

Section 220(d) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added a new subparagraph to the Act to establish an annual target for reductions in MPFS expenditures resulting from adjustments to relative values of misvalued codes. Under the Act, if the estimated net reduction in expenditures for a year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the MPFS in accordance with the existing budget neutrality requirement of the Act. The provision also specifies that the amount by which such reduced expenditures exceeds the target for a given year shall be treated as a net reduction in expenditures for the succeeding year, for purposes of determining whether the target has been met in that subsequent year. The Act defines the target recapture amount as the amount by which the target for the year is exceeded by the estimated net reduction in expenditures under the MPFS resulting from adjustments to RVUs for misvalued codes. The Act also specifies that, if the estimated net reduction in MPFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in the Act. Section 220(d) of the 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 MPFS for each of those 4 years.

Section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113-295, enacted December 19, 2014) amended the Act to accelerate the application of the MPFS expenditure reduction target to CYs 2016, 2017, and 2018, and to set a 1 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018. As a result of these provisions, if the estimated net reduction for a given year is less than the target for that year, payments under the fee schedule will be reduced.

CMS is proposing a methodology to implement this statutory provision in a manner consistent with the broader statutory construct of the MPFS. In developing this proposed methodology, they have identified several aspects of our approach for which they are specifically seeking comment.

Distinguishing “Misvalued Code” Adjustments from Other RVU Adjustments

CMS points out that the identification of particular codes as potentially misvalued has led to the review and revaluation of related codes, and frequently, to revisions to the underlying coding for large sets of related services. Similarly, the review of individual codes has initiated reviews and proposals to make broader adjustments to values for codes across the MPFS, such as when the review of a series of imaging codes prompted a RUC recommendation and CMS proposal to update the direct PE inputs for imaging services to assume digital instead of film costs. This change, originating through the misvalued code initiative, resulted in a significant reduction in RVUs for a large set of MPFS services, even though the majority of affected codes were not initially identified through potentially misvalued code screens. Finally, due to both the relativity inherent in the MPFS ratesetting process and the budget neutrality requirements specified in the
Act, adjustments to the RVUs for individual services necessarily result in the shifting of RVUs to broad sets of other services across the MPFS.

After considering several options, CMS believes that the best approach is to define the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values. This would limit the pool of RVU adjustments used to calculate the net reduction in expenditures to those for the services for which individual, comprehensive review or broader proposed adjustments have resulted in changes to service-level inputs of work RVUs, direct PE inputs, or MP RVUs, as well as services directly affected by changes to coding for related services. For example, coding changes in certain codes can sometimes necessitate revaluations for related codes that have not been reviewed as misvalued codes, because the coding changes have also affected the scope of the related services. This definition would incorporate all reduced expenditures from revaluations for services that are deliberatively addressed as potentially misvalued codes, as well as those for services with broadbased adjustments like film-to-digital and services that are redefined through coding changes as a result of the review of misvalued codes.

Because the annual target is calculated by measuring changes from one year to the next, CMS also considered how to account for changes in values that are best measured over 3 years, instead of 2 years. Under the current process, the overall change in valuation for many misvalued codes is measured across values for 3 years: the original value in the first year, the interim final value in the second year, and the finalized value in the third year. However, the straightforward calculation of the target would only compare changes between 2 years and not among 3 years, so the contribution of a particular change towards the target for any single year would be measured against only the preceding year without regard to the overall change that takes place over 3 years.

For recent years, interim final values for misvalued codes (year 2) have generally reflected reductions relative to original values (year 1), and for most codes, the interim final values (year 2) are maintained and finalized (year 3). However, when values for particular codes have changed between the interim final (year 2) and final values (year 3) based on public comment, the general tendency has been that codes increase in the final value (year 3) relative to the interim final value (year 2), even in cases where the final value (year 3) represents a decrease from the original value (year 1). Therefore, for these codes, the year 2 changes compared to year 1 would risk over-representing the overall reduction, while the year 3 to year 2 changes would represent an increase in value. If there were similar targets in every MPFS year, and a similar number of misvalued code changes made on an interim final basis, the incongruence in measuring what is really a 3-year change in 2-year increments might not be particularly problematic since each year’s calculation would presumably include a similar number of codes measured between years 1 and 2 and years 2 and 3.

However, including changes that take place over 3 years is particularly problematic for calculating the target for CY 2016 for two reasons. First, CY 2015 was the final full year of establishing interim final values for all new, revised, and potentially misvalued codes. Starting with this proposed rule, CMS is proposing and finalizing values for a significant portion of misvalued codes during one calendar year. Therefore, CY 2015 will include a disproportionate
number of services that would be measured between years 2 and 3 relative to the services measured between 1 and 2 years. Second, because there was no target for CY 2015, any reductions that occurred on an interim final basis for CY 2015 were not counted toward achievement of a target. If CMS were to include any upward adjustments made to these codes based on public comment as “misvalued code” changes for CY 2016, they would effectively be counting the service-level increases for 2016 (year 3) relative to 2015 (year 2) against achievement of the target without any consideration to the service-level changes relative to 2014 (year 1), even in cases where the overall change in valuation was negative.

Therefore, **CMS is proposing to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.**

CMS notes that the impact of interim final values in the calculation of targets for future years will be diminished as they transition to proposing values for almost all new, revised, and potentially misvalued codes in the proposed rule. They anticipate a smaller number of interim final values for CY 2016 relative to CY 2015. For calculation of the CY 2018 target, they anticipate almost no impact based on misvalued code adjustments that occur over multiple years.

**Calculating “Net Reduction”**

Once the RVU changes attributable to misvalued codes are identified, estimated net reductions would be calculated summing the decreases and offsetting any applicable increases in valuation within the changes defined as misvalued, as described above. Because the provision only explicitly addresses reductions, and CMS recognizes many stakeholders will want to maximize the overall magnitude of the measured reductions in order to prevent an overall reduction to the MPFS conversion factor, CMS considered the possibility of ignoring the applicable increases in valuation in the calculation of net reduction. However, CMS believes that the requirement to calculate “net” reductions implies that they are to take into consideration both decreases and increases. Additionally, they believe this approach may be the only practical one due to the presence of new and deleted codes on an annual basis.

For example, a service that is described by a single code in a given year, like intensity modulated radiation therapy (IMRT) treatment delivery, could be addressed as a misvalued service in a subsequent year through a coding revision that splits the service into two codes, “simple” and “complex.” If CMS counted only the reductions in RVUs, they would count only the change in value between the single code and the new code that describes the “simple” treatment delivery code. In this scenario, the change in value from the single code to the new “complex” treatment delivery code would be ignored, so that even if there were an increase in the payment for IMRT treatment delivery service(s) overall, the mere change in coding would contribute inappropriately to a “net reduction in expenditures.” Therefore, **CMS is proposing to net the increases and decreases in values for services, including those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes.**
CMS recognizes that the most straightforward method to estimating the net reduction in expenditures due to adjustments to RVUs for misvalued codes is to compare the total RVUs of the relevant set of codes (by volume) in the current year to the update year, and divide that by the total RVUs for all codes (by volume) for the current year. This approach is intuitive and relatively easy to replicate. However, CMS believes this method is imprecise for several reasons. First, and most significantly, the code-level PE RVUs in the update year include either increases due to the redistribution of RVUs from other services or reductions due to increases in PE for other services. Second, because relativity for work RVUs is maintained through annual adjustments to the CF, the precise value of a work RVU in any given year is adjusted based on the total number of work RVUs in that year. Finally, relativity for the MP RVUs is maintained by both redistribution of MP RVUs and adjustments to the CF, when necessary (under the proposed methodology this is true annually; based on the established methodology the redistribution of the MP RVUs only takes place once every 5 years and the CF is adjusted otherwise). Therefore, to make a more precise assessment of the net reduction in expenditures that are the result of adjustments to the RVUs for misvalued codes, CMS would need to compare, for the included codes, the update year’s total work RVUs (by volume), direct PE RVUs (by volume), indirect PE RVUs (by volume), and MP RVUs (by volume) to the same RVUs in the current year, prior to the application of any scaling factors or adjustments. This would make for a direct comparison between years.

However, this approach would mean that the calculation of the net reduction in expenditures would occur within various steps of the MPFS ratesetting methodology. While CMS believes that this approach would be transparent and external stakeholders could replicate this method, it may be difficult and time-consuming for stakeholders to do so. CMS also noted that when they modeled the interaction of the phase-in legislation and the calculation of the target using this approach during the development of this proposal, there were methodological challenges in making these calculations. When they simulated the two approaches using information from prior MPFS years, they found that both approaches generally resulted in similar estimated net reductions. After considering these options, CMS is proposing to use the approach of comparing the total RVUs (by volume) for the relevant set of codes in the current year to the update year, and divide that result by the total RVUs (by volume) for the current year. CMS seeks comment on whether comparing the update year’s work RVUs, direct PE RVUs, indirect PE RVUs, and MP RVUs for the relevant set of codes (by volume) prior to the application of any scaling factors or adjustments to those of the current year would be a preferable methodology for determining the estimated net reduction.

Estimating the Target for CY 2016

For CY 2016, there will still be a significant number of codes valued not in the proposed rule but in the final rule with comment period. In future years (with the exception of entirely new services), all codes, even those for which CMS does not receive RUC recommendations in time for the proposed rule, will be in the proposed rule for the subsequent year and not in the final rule with comment period. Therefore, for CY 2016, unlike for the targets for CY 2017 and CY 2018, because CMS will not be able to calculate a realistic estimate of the target amount at the time the
proposed rule is published, CMS did not incorporate the impact of the target into the calculation of the proposed MPFS payment rates. However, because they would apply any required budget neutrality adjustment related to this provision to the conversion factor, the proposed RVUs for individual services in this proposed rule would be the same, regardless of the estimate of the target.

CMS addresses an interim estimate of the estimated net reduction in expenditures relative to the 1 percent target for CY 2016 in the regulatory impact analysis section of the proposed rule (discussed in the first section of this summary). The net reduction is approximately 0.25 percent of the estimated amount of expenditures under the fee schedule for CY 2016.

**Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements (Page 289)**

CMS is proposing to amend §410.26(b)(5) to state that the physician or other practitioner who bills for incident to services must also be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services. Also, to further clarify the meaning of the proposed amendment to this regulation, CMS is proposing to remove the last sentence from §410.26(b)(5) specifying that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

CMS is proposing to amend the regulation to explicitly prohibit auxiliary personnel from providing incident to services who have either been excluded from Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or who have had their enrollment revoked for any reason. These excluded or revoked individuals are already prohibited from providing services to Medicare beneficiaries, so this proposed revision is an additional safeguard to ensure that these excluded or revoked individuals are not providing incident to services and supplies under the direct supervision of a physician or other authorized supervising practitioner. These proposed revisions to the incident to regulations will provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services and supplies that are not furnished in compliance with program requirements.

While CMS believes that the initial responsibility of compliance rests with the practitioner, they invite comments through this proposed rule about possible approaches that could be taken to improve their ability ensure that incident to services are provided to beneficiaries by qualified individuals in a manner consistent with Medicare statute and regulations. They invite commenters to consider the options CMS will consider, such as creating new categories of enrollment, implementing a mechanism for registration short of full enrollment, requiring the use of claim elements such as modifiers to identify the types of individuals providing services, or relying on post-payment audits, investigations and recoupments by CMS contractors such as Recovery Auditors or Program Integrity Contractors. CMS will consider these comments in the course of implementing the proposals they finalize in rulemaking for CY 2016, and further, if CMS decides in the future that additional regulations or guidance will be necessary to monitor compliance with these or other requirements surrounding incident to services.
Portable X-Ray: Billing of the Transportation Fee (Page 295)

CMS is proposing to clarify that when more than one patient is X-rayed at the same location, the single transportation payment under the MPFS is to be prorated among all patients (Medicare Parts A and B, and non-Medicare) receiving portable X-ray services during that trip, regardless of their insurance status. For example, for portable x-ray services furnished at a SNF, CMS believes that the transportation fee should be allocated among all patients receiving portable X-ray services at the same location in a single trip irrespective of whether the patient is in a Part A stay, a Part B patient, or not a Medicare beneficiary at all. If the patient is in a Part A SNF stay, payment for the allocated portion of the transportation fee (and the X-ray) would be the SNF’s responsibility. For a privately insured patient, it would be the responsibility of that patient’s insurer. For a Medicare Part B patient, payment would be made under Part B for the share of the transportation fee attributable to that patient. CMS welcomes comments on this proposal to determine Medicare Part B’s portion of the transportation payment by prorating the single fee among all patients.


Section 101(e)(7) of the Medicare Access and CHIP Reauthorization Act (MACRA) requires the Secretary, in consultation with the Office of Inspector General (OIG), to study and report to the Congress on fraud related to alternative payment models under the Medicare program (the APM Report). The Secretary must study the applicability of the federal fraud prevention laws to items and services furnished under title XVIII of the Act for which payment is made under an alternative payment model, identify aspects of alternative payment models that are vulnerable to fraudulent activity, and examine the implications of waivers to the fraud prevention laws to support alternative payment models. The Secretary must include in the APM Report the results of her study and recommendations for actions to reduce the vulnerabilities of Medicare alternative payment models, including possible changes in federal fraud prevention laws to reduce such vulnerabilities. This report must be issued no later than 2 years after the enactment of MACRA.

Section 512(b) of MACRA requires the Secretary, in consultation with OIG, to submit to the Congress a report with options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that would otherwise be subject civil money penalties in paragraphs (1) and (2) of section 1128A(b) of the Act and similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency (the Gainsharing Report). The Gainsharing Report must address whether the recommended changes should apply to ownership interests, compensation arrangements, or other relationships. The Gainsharing Report must also describe how the recommendations address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care. Further, the Secretary’s Gainsharing Report must consider whether a portion of any savings generated by such arrangements should accrue to the Medicare program. This report must be issued no later than 12 months after the enactment of MACRA.
CMS is soliciting comments regarding the impact of the physician self-referral law on health care delivery and payment reform. They have posed the following questions to encourage robust commentary.

- Does the physician self-referral law generally and, in particular, the “volume or value” and “other business generated” standards set out in CMS regulations, pose barriers to or limitations on achieving clinical and financial integration? If so, are the barriers or limitations more pronounced for hospitals than for other providers or suppliers because all Medicare revenue is from DHS (and, thus, any compensation might be considered to take into account the volume or value of referrals or other business generated by the physician to whom it is paid)?
- Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?
- Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted? What conditions should CMS place on such financial relationships to protect against program or patient abuse? Should a new exception be structured to protect services, rather than a specific type of financial relationship, when established conditions are met (similar to the in-office ancillary services exception at §411.355(b), which protects referrals for certain services performed by physician practices that meet the requirements of §411.352)? Would legislative action be necessary to establish exceptions to support alternative payment models?
- Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?
- Is there need for new exceptions to the physician self-referral law to support shared savings or “gainsharing” arrangements? If so, what types of financial relationships should be excepted? What conditions should CMS place on such financial relationships to address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care? Would legislative action be necessary to establish exceptions to support shared savings or “gainsharing” arrangements?
- Should certain entities, such as those considered to provide high-value care to Medicare beneficiaries, be permitted to compensate physicians in ways that other entities may not? For example, should CMS permit hospitals that meet established quality and value metrics under the Hospital VBP to pay bonus compensation from DHS revenues to physicians who help the hospital meet those metrics? If so, what conditions should CMS impose to protect against program and patient abuse? How should they define “high-value care” or “high-value entity”? Are there standards other than the value of the care provided to patients that would be appropriate as threshold standards for permitting a hospital or other entity furnishing DHS to compensate physicians in ways that other entities may not?
- Could existing exceptions, such as the exception at §411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and
payment model sponsored by a non-federal payor? If so, what conditions should CMS impose to protect against program and patient abuse from the compensation arrangements resulting from participation in such models?

- Have litigation and judicial rulings on issues such as compensation methodologies, fair market value, or commercial reasonableness generated a need for additional guidance from CMS on the interpretation of the physician self-referral law or the application of its exceptions? CMS is particularly interested in the need for guidance in the context of delivery system reform.

- Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at §411.357(p) for indirect compensation arrangements?

- Given the changing incentives for health care providers under delivery system reform, should CMS deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should CMS impose for this deemed status to ensure that compensation paid to a physician is sufficiently attenuated from the volume or value of his referrals to or other business generated for the entity paying the compensation? Should CMS apply such a deeming provision only to certain types of entities furnishing DHS, such as hospitals that provide high value care to Medicare beneficiaries?

Improving Payment Accuracy for Primary Care and Care Management Services (Page 86)

CMS is interested in receiving public comments on ways to recognize the 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. The resource costs of this work may include the time and intensity related to the management of both long-term and, in some cases, episodic conditions. In order to appropriately recognize the different resource costs for this additional cognitive work within the structure of MPFS resource-based payments, CMS is particularly interested in codes that could be used in addition to, not instead of, the current E/M codes.

CMS strongly encourages stakeholders to comment on the topic of coding and billing of care management in order to assist them in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. CMS anticipates using this approach, which would parallel their multiyear approach for implementing chronic care management (CCM) and transitional care management (TCM) services, in order to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

Establishing Separate Payment for Collaborative Care

CMS recognizes that the care and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or common behavioral health conditions often requires extensive discussion, information-sharing and planning between a primary care physician and a specialist.
In considering how to improve the accuracy of payments for care coordination particularly for patients requiring more extensive care, CMS is seeking comment on how Medicare might accurately account for the resource costs of a more robust interprofessional consultation within the current structure of MPFS payment. CMS is interested in stakeholder input regarding the parameters of, and resources involved in these collaborations between a specialist and primary care practitioner, especially in the context of the structure and valuation of current E/M services. In particular, CMS is interested in comments about how these collaborations could be distinguished from the kind of services included in other E/M services, how these services could be described if stakeholders believe the current CPT codes are not adequate, and how these services should be valued on the MPFS. CMS is also interested in comments on whether they should tie those interprofessional consultations to a beneficiary encounter and on developing appropriate beneficiary protections to ensure that beneficiaries are fully aware of the involvement of the specialist in the beneficiary’s care and the associated benefits of the collaboration between the primary care physician and the specialist physician prior to being billed for such services.

Additionally, CMS is seeking comment on whether this kind of care might benefit from inclusion in a CMMI model that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variation of payment amounts for the consulting and the primary care practitioners. Without such protections, beneficiaries could be responsible for coinsurance for services of physicians whose role in the beneficiary’s care is not necessarily understood by the beneficiary. Finally, CMS is seeking comment on key technology supports needed to support collaboration between specialist and primary care practitioners in support of high quality care management services, on whether they should consider including technology requirements as part of any proposed services, and on how such requirements could be implemented in a way that minimizes burden on providers. CMS strongly encourages stakeholders to comment on this topic in order to assist in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017.